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Public Health

42

PART 430 TO END
Revised as of October 1, 1988

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PART 430 TO END

Revised as of October 1, 1988

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AS OF OCTOBER 1, 1988

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Cite this Code: CFR

To cite the regulations in this volume use title, part and section number. Thus, 42 CFR 430.0 *refers to* Title *42,* Part *430,* section *0.*

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Title 1 through Title 16	as of January 1
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Title 42 through Title 50	as of October 1

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JOHN E. BYRNE,
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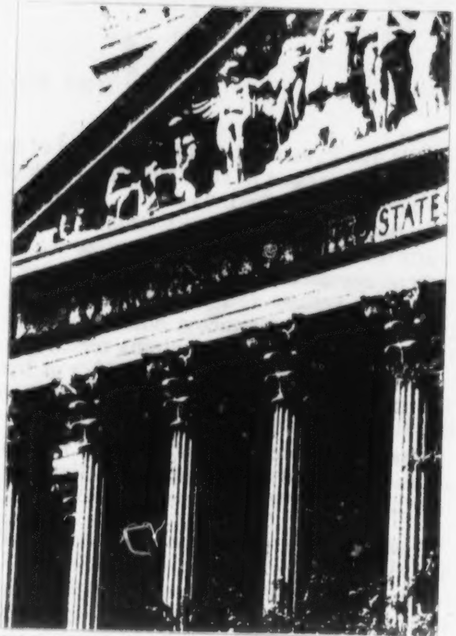

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Title 42—Public Health

(Part 430 to End)

Part

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CHAPTER V—Office of Inspector General-Health Care, Department of Health and Human Services 1000

CHAPTER IV—HEALTH CARE FINANCING ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES—(Continued)

EDITORIAL NOTE: Nomenclature changes affecting Chapter IV of Title 42 appear at 45 FR 24882, Apr. 11, 1980, 45 FR 53806, Aug. 13, 1980, and 50 FR 33034, Aug. 16, 1985.

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SUBCHAPTER C—MEDICAL ASSISTANCE PROGRAMS

PART 430—GRANTS TO STATES FOR MEDICAL ASSISTANCE PROGRAMS

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AUTHORITY: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

SOURCE: 53 FR 36571, Sept. 21, 1988, unless otherwise noted.

EFFECTIVE DATE NOTE: At 53 FR 36571, Sept. 21, 1988, Part 430 was revised, effective October 21, 1988. For the convenience of the user, the superseded text follows this revised Part 430.

Subpart A—Introduction; General Provisions

§ 430.0 Program description.

Title XIX of the Social Security Act, enacted in 1965, authorizes Federal grants to States for medical assistance to low-income persons who are age 65 or over, blind, disabled, or members of families with dependent children or qualified pregnant women or children. The program is jointly financed by the Federal and State governments and administered by States. Within broad Federal rules, each State decides eligible groups, types and range of services, payment levels for services, and administrative and operating procedures. Payments for services are made directly by the State to the individuals or entities that furnish the services.

§ 430.1 Scope of Subchapter C.

The regulations in Subchapter C set forth State plan requirements, standards, procedures, and conditions for obtaining Federal financial participation (FFP). Each part (or subpart of section) in the subchapter describes the specific statutory basis for the regulation. However, where the basis is the Secretary's general authority to issue regulations for any program under the Act (section 1102 of the Act), or his general authority to prescribe State plan requirements needed for proper and efficient administration of the plan (section 1902(a)(4)), those statutory provisions are simply cited without further description.

§ 430.2 Other applicable Federal regulations.

Other regulations applicable to State Medicaid programs include the following:

(a) 5 CFR Part 900, Subpart F, Administration of the Standards for a Merit System of Personnel Administration.

(b) The following HHS Regulations in 45 CFR Subtitle A:

Part 16—Department Grant Appeals Process.

Part 74—Administration of Grants.

Part 80—Nondiscrimination Under Programs Receiving Federal Assistance Through the Department of Health and Human Services: Effectuation of Title VI of the Civil Rights Act of 1964.

Part 81—Practice and Procedure for Hearings Under 45 CFR Part 80.

Part 84—Nondiscrimination on the Basis of Handicap in Programs and Activities Receiving or Benefiting From Federal Financial Assistance.

Part 95—General Administration—grant programs (public assistance and medical assistance).

§ 430.3 Appeals under Medicaid.

Three distinct types of disputes may arise under Medicaid.

(a) *Compliance with Federal requirements.* Disputes that pertain to whether a State's plan or proposed plan amendments, or its practice under the plan meet or continue to meet Federal requirements are subject to the hearing provisions of Subpart D of this part.

(b) *FFP in Medicaid expenditures.* Disputes that pertain to disallowances of FFP in Medicaid expenditures (mandatory grants) are heard by the Departmental Grants Appeals Board (the Board) in accordance with procedures set forth in 45 CFR Part 16.

(c) *Discretionary grants disputes.* Disputes pertaining to discretionary grants, such as grants for special demonstration projects under sections 1110 and 1115 of the Act, which may be awarded to a Medicaid agency, are also heard by the Board. 45 CFR Part 16, Appendix A, lists all the types of disputes that the Board hears.

Subpart B—State Plans

§ 430.10 The State plan.

The State plan is a comprehensive written statement submitted by the agency describing the nature and scope of its Medicaid program and giving assurance that it will be administered in conformity with the specific requirements of title XIX, the regulations in this Chapter IV, and other applicable official issuances of the Department. The State plan contains all information necessary for HCFA to determine whether the plan can be approved to serve as a basis for Federal financial participation (FFP) in the State program.

§ 430.12 Submittal of State plans and plan amendments.

(a) *Format.* A State plan for Medicaid consists of preprinted material that covers the basic requirements, and individualized content that reflects the characteristics of the particular State's program.

(b) *Governor's review*—(1) *Basic rules.* Except as provided in paragraph (b)(2) of this section—

(i) The Medicaid agency must submit the State plan and State plan amendments to the State Governor or his designee for review and comment before submitting them to the HCFA regional office.

(ii) The plan must provide that the Governor will be given a specific period of time to review State plan amendments, long-range program planning projections, and other periodic reports on the Medicaid program, excluding periodic statistical, budget and fiscal reports.

(iii) Any comments from the Governor must be submitted to HCFA with the plan or plan amendment.

(2) *Exceptions.* (i) Submission is not required if the Governor's designee is the head of the Medicaid agency.

(ii) Governor's review is not required for preprinted plan amendments that are developed by HCFA if they provide absolutely no options for the State.

(c) *Plan amendments.* (1) The plan must provide that it will be amended whenever necessary to reflect—

(i) Changes in Federal law, regulations, policy interpretations, or court decisions; or

(ii) Material changes in State law, organization, or policy, or in the State's operation of the Medicaid program.

(2) Prompt submittal of amendments is necessary—

(i) So that HCFA can determine whether the plan continues to meet the requirements for approval; and

(ii) To ensure the availability of FFP in accordance with § 430.20.

§ 430.14 Review of State plan material.

HCFA regional staff reviews State plans and plan amendments, discusses any issues with the Medicaid agency, and consults with central office staff on questions regarding application of Federal policy.

§ 430.15 Basis and authority for action on State plan material.

(a) *Basis for action.* (1) Determinations as to whether State plans (including plan amendments and administrative practice under the plans) originally meet or continue to meet the requirements for approval are based on relevant Federal statutes and regulations.

(2) Guidelines are furnished to assist in the interpretation of the regulations.

(b) *Approval authority.* The Regional Administrator exercises delegated authority to approve the State plan and plan amendments on the basis of policy statements and precedents previously approved by the Administrator.

(c) *Disapproval authority.* (1) The Administrator retains authority for determining that proposed plan material is not approvable or that previously approved material no longer meets the requirements for approval.

(2) The Administrator does not make a final determination of disapproval without first consulting the Secretary.

§ 430.16 Timing and notice of action on State plan material.

(a) *Timing.* (1) A State plan or plan amendment will be considered approved unless HCFA, within 90 days after receipt of the plan or plan amendment in the regional office, sends the State—

(i) Written notice of disapproval; or

(ii) Written notice of any additional information it needs in order to make a final determination.

(2) If HCFA requests additional information, the 90-day period for HCFA action on the plan or plan amendment begins on the day it receives that information.

(b) *Notice of final determination.* (1) The Regional Administrator or the Administrator notifies the Medicaid agency of the approval of a State plan or plan amendment.

(2) Only the Administrator gives notice of disapproval of a State plan or plan amendment.

§ 430.18 Administrative review of action on State plan material.

(a) *Request for reconsideration.* Any State dissatisfied with the Administrator's action on plan material under § 430.15 may, within 60 days after receipt of the notice provided under § 430.16(b), request that the Administrator reconsider the issue of whether the plan or plan amendment conforms to the requirements for approval.

(b) *Notice and timing of hearing.* (1) Within 30 days after receipt of the request, the Administrator notifies the State of the time and place of the hearing.

(2) The hearing takes place not less than 30 days nor more than 60 days after the date of the notice, unless the State and the Administrator agree in writing on an earlier or later date.

(c) *Hearing procedures.* The hearing procedures are set forth in Subpart D of this part.

(d) *Decision.* A decision affirming, modifying, or reversing the Administrator's original determination is made in accordance with § 430.102.

(e) *Effect of hearing decision.* (1) Denial of Federal funds, if required by the Administrator's original determination, will not be delayed pending a hearing decision.

(2) However, if the Administrator determines that his or her original decision was incorrect, HCFA pays the

State a lump sum equal to any funds incorrectly denied.

§ 430.20 Effective dates of State plans and plan amendments.

For purposes of FFP, the following rules apply:

(a) *New plans.* The effective date of a new plan—

(1) May not be earlier than the first day of the quarter in which an approvable plan is submitted to the regional office; and

(2) With respect to expenditures for medical assistance, may not be earlier than the first day on which the plan is in operation on a statewide basis.

(b) *Plan amendment.* (1) For a plan amendment that provides additional services to individuals eligible under the approved plan, or makes additional groups eligible for services provided under the approved plan, the effective date is determined in accordance with paragraph (a) of this section.

(2) For other plan amendments, the effective date may be a date requested by the State if HCFA approves it.

Subpart C—Grants; Reviews and Audits; Withholding for Failure To Comply; Deferral and Disallowance of Claims; Reduction of Federal Medicaid Payments

§ 430.30 Grants procedures.

(a) *General provisions.* (1) Once HCFA has approved a State plan, it makes quarterly grant awards to the State to cover the Federal share of expenditures for services, training, and administration.

(2) The amount of the quarterly grant is determined on the basis of information submitted by the State agency (in quarterly estimate and quarterly expenditure reports) and other pertinent documents.

(b) *Quarterly estimates.* The Medicaid agency must submit Form HCFA-25 (Medicaid Program Budget Report; Quarterly Distribution of Funding Requirements) to the central office (with a copy to the regional office) 45 days before the beginning of each quarter.

(c) *Expenditure reports.* (1) The State must submit Form HCFA-64 (Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program) to the central office (with a copy to the regional office) not later than 30 days after the end of each quarter.

(2) This report is the State's accounting of actual recorded expenditures. The disposition of Federal funds may not be reported on the basis of estimates.

(d) *Grant award*—(1) *Computation by HCFA.* Regional office staff analyzes the State's estimates and sends a recommendation to the central office. Central office staff considers the State's estimates, the regional office recommendations and any other relevant information, including any adjustments to be made under paragraph (d)(2) of this section, and computes the grant.

(2) *Content of award.* The grant award computation form shows the estimate of expenditures for the ensuring quarter, and the amounts by which that estimate is increased or decreased because of an underestimate or overestimate for prior quarters, or for any of the following reasons:

(i) Penalty reductions imposed by law.

(ii) Accounting adjustments.

(iii) Deferrals or disallowances.

(iv) Interest assessments.

(v) Mandated adjustments such as those required by section 1914 of the Act.

(3) *Effect of award.* The grant award authorizes the State to draw Federal funds as needed to pay the Federal share of disbursements.

(4) *Drawing procedure.* The draw is through a commercial bank and the Federal Reserve system against a continuing letter of credit certified to the Secretary of the Treasury in favor of the State payee. (The letter of credit payment system was established in accordance with Treasury Department regulations—Circular No. 1075.)

(e) *General administrative requirements.* With the following exceptions, the provisions of 45 CFR Part 74, which establish uniform administrative requirements and cost principles, apply to all grants made to States under this subpart:

45 CFR Part 74

Subpart G—Matching and Cost Sharing
Subpart I—Financial Report Requirements

§ 430.32 Program reviews.

(a) *Review of State and local administration.* In order to determine whether the State is complying with the Federal requirements and the provisions of its plan, HCFA reviews State and local administration through analysis of the State's policies and procedures, on-site review of selected aspects of agency operation, and examination of samples of individual case records.

(b) *Quality control program.* The State itself is required to carry out a continuing quality control program as set forth in Part 431, Subpart P, of this chapter.

(c) *Action on review findings.* If Federal or State reviews reveal serious problems with respect to compliance with any Federal requirement, the State must correct its practice accordingly.

§ 430.33 Audits.

(a) *Purpose.* The Department's Office of Inspector General (OIG) periodically audits State operations in order to determine whether—

(1) The program is being operated in a cost-efficient manner; and

(2) Funds are being properly expended for the purposes for which they were appropriated under Federal and State law and regulations.

(b) *Reports.* (1) The OIG releases audit reports simultaneously to State officials and the Department's program officials.

(2) The reports set forth OIG opinion and recommendations regarding the practices it reviewed, and the allowability of the costs it audited.

(3) Cognizant officials of the Department make final determinations on all audit findings.

(c) *Action on audit exceptions*—(1) *Concurrence or clearance.* The State agency has the opportunity of concurring in the exceptions or submitting additional facts that support clearance of the exceptions.

(2) *Appeal.* Any exceptions that are not disposed of under paragraph (c)(1) of this section are included in a disallowance letter that constitutes the Department's final decision unless the State requests reconsideration by the Grant Appeals Board. (Specific rules are set forth in § 430.42.)

(3) *Adjustment.* If the decision by the Board requires an adjustment of FFP, either upward or downward, a subsequent grant award promptly reflects the amount of increase or decrease.

§ 430.35 Withholding of payment for failure to comply with Federal requirements.

(a) *Basis for withholding.* HCFA withholds payments to the State, in whole or in part, only if, after giving the agency reasonable notice and opportunity for a hearing in accordance with Subpart D of this part, the Administrator finds—

(1) That the plan no longer complies with the provisions of section 1902 of the Act; or

(2) That in the administration of the plan there is failure to comply substantially with any of those provisions.

(Hearings under Subpart D are generally not called until a reasonable effort has been made to resolve the issues through conferences and discussions. These may be continued even if a date and place have been set for the hearing.)

(b) *Noncompliance of the plan.* A question of noncompliance of a State plan may arise from an unapprovable change in the approved State plan or the failure of the State to change its approved plan to conform to a new Federal requirement for approval of State plans.

(c) *Noncompliance in practice.* A question of noncompliance in practice may arise from the State's failure to actually comply with a Federal requirement, regardless of whether the plan itself complies with that requirement.

(d) *Notice and implementation of withholding.* If the Administrator makes a finding of noncompliance under paragraph (a) of this section, the following rules apply:

(1) The Administrator notifies the State:

(i) That no further payments will be made to the State (or that payments will be made only for those portions or aspects of the program that are not affected by the noncompliance); and

(ii) That the total or partial withholding will continue until the Administrator is satisfied that the State's plan and practice are, and will continue to be, in compliance with Federal requirements.

(2) HCFA withholds payments, in whole or in part, until the Administrator is satisfied regarding the State's compliance.

§ 430.38 Judicial review.

(a) *Right to judicial review.* Any State dissatisfied with the Administrator's final determination on approvability of plan material (§ 430.18) or compliance with Federal requirements (§ 430.35) has a right to judicial review.

(b) *Petition for review.* (1) The State must file a petition for review with the U.S. Court of Appeals for the circuit in which the State is located, within 60 days after it is notified of the determination.

(2) The clerk of the court will file a copy of the petition with the Administrator and the Administrator will file in the court the record of the proceedings on which the determination was based.

(c) *Court action.* (1) The court is bound by the Administrator's findings of fact if they are supported by substantial evidence.

(2) The court has jurisdiction to affirm the Administrator's decision, to set it aside in whole or in part, or, for good cause, to remand the case for additional evidence.

(d) *Response to remand.* (1) If the court remands the case, the Administrator may make new or modified findings of fact and may modify his or her previous determination.

(2) The Administrator will certify to the court the transcript and record of the further proceedings.

(e) *Review by the Supreme Court.* The judgment of the appeals court is subject to review by the U.S. Supreme Court upon certiorari or certification, as provided in 28 U.S.C. 1254.

§ 430.40 Deferral of claims for FFP.

(a) *Requirements for deferral.* Payment of a claim or any portion of a claim for FFP is deferred only if—

(1) The Regional Administrator or the Administrator questions its allowability and needs additional information in order to resolve the question; and

(2) HCFA takes action to defer the claim (by excluding the claimed amount from the grant award) within 60 days after the receipt of a Quarterly Statement of Expenditures (prepared in accordance with HCFA instructions) that includes that claim.

(b) *Notice of deferral and State's responsibility.* (1) Within 15 days of the action described in paragraph (a)(2) of this section, the Regional Administrator sends the State a written notice of deferral that—

(i) Identifies the type and amount of the deferred claim and specifies the reason for deferral; and

(ii) Requests the State to make available all the documents and materials the regional office then believes are necessary to determine the allowability of the claim.

(2) It is the responsibility of the State to establish the allowability of a deferred claim.

(c) *Handling of documents and materials.* (1) Within 60 days (or within 120 days if the State requests an extension) after receipt of the notice of deferral, the State must make available to the regional office, in readily reviewable form, all requested documents and materials except any that it identifies as not being available.

(2) Regional office staff usually initiates review within 30 days after receipt of the documents and materials.

(3) If the Regional Administrator finds that the materials are not in readily reviewable form or that additional information is needed, he or she promptly notifies the State that it has 15 days to submit the readily reviewable or additional materials.

(4) If the State does not provide the necessary materials within 15 days, the Regional Administrator disallows the claim.

(5) The Regional Administrator has 90 days, after all documentation is

available in readily reviewable form, to determine the allowability of the claim.

(6) If the Regional Administrator cannot complete review of the material within 90 days, HCFA pays the claim, subject to a later determination of allowability.

(d) *Effect of decision to pay a deferred claim.* Payment of a deferred claim under paragraph (c)(6) of this section does not preclude a subsequent disallowance based on the results of an audit or financial review. (If there is a subsequent disallowance, the State may request reconsideration as provided in paragraph (e)(2) of this section.)

(e) *Notice and effect of decision on allowability.* (1) The Regional Administrator or the Administrator gives the State written notice of his or her decision to pay or disallow a deferred claim.

(2) If the decision is to disallow, the notice informs the State of its right to reconsideration in accordance with 45 CFR Part 16.

§ 430.42 Disallowance of claims for FFP.

(a) *Notice of disallowance and of right to reconsideration.* When the Regional Administrator or the Administrator determines that a claim or portion of claim is not allowable, he or she promptly sends the State a disallowance letter that includes the following, as appropriate:

(1) The date or dates on which the State's claim for FFP was made.

(2) The time period during which the expenditures in question were made or claimed to have been made.

(3) The date and amount of any payment or notice of deferral.

(4) A statement of the amount of FFP claimed, allowed, and disallowed and the manner in which these amounts were computed.

(5) Findings of fact on which the disallowance determination is based or a reference to other documents previously furnished to the State or included with the notice (such as a report of a financial review or audit) which contain the findings of fact on which the disallowance determination is based.

(6) Pertinent citations to the law, regulations, guides and instructions supporting the action taken.

(7) A request that the State make appropriate adjustment in a subsequent expenditure report.

(8) Notice of the State's right to request reconsideration of the disallowance and the time allowed to make the request.

(9) A statement indicating that the disallowance letter is the Department's final decision unless the State requests reconsideration under paragraph (b)(2) of this section.

(b) *Reconsideration of FFP disallowance.* (1) The Departmental Grant Appeals Board reviews disallowances of FFP under title XIX.

(2) A State that wishes to request reconsideration must submit the request to the Chairperson, Departmental Grants Appeals Board, within 30 days after receipt of the disallowance letter, and include—

(i) A copy of the disallowance letter;

(ii) A statement of the amount in dispute; and

(iii) A brief statement of why the disallowance is wrong.

(c) *Reconsideration procedures.* The reconsideration procedures are those set forth in 45 CFR Part 16 for Medicaid and for many other programs administered by the Department.

(d) *Implementation of decisions.* If the reconsideration decision requires an adjustment of FFP, either upward or downward, a subsequent grant award promptly reflects the amount of increase or decrease.

§ 430.45 Reduction of Federal Medicaid payments.

(a) *Methods of reduction.* HCFA may reduce Medicaid payments to a State as required under the Act by reducing—

(1) The Federal Medical Assistance Percentage;

(2) The amount of State expenditures subject to FFP;

(3) The rates of FFP; or

(4) The amount otherwise payable to the State.

(b) *Right to reconsideration.* A state that receives written final notice of a reduction under paragraph (a) of this section has a right to reconsideration. The provisions of § 430.42 (b) and (c) apply.

(c) *Other applicable rules.* Other rules regarding reduction of Medicaid payments are set forth in Parts 433 and 447 of this chapter.

§ 430.48 Repayment of Federal funds by installments.

(a) *Basic conditions.* When Federal payments have been made for claims that are later found to be unallowable, the State may repay the Federal Funds by installments if the following conditions are met:

(1) The amount to be repaid exceeds 2½ percent of the estimated or actual annual State share for the Medicaid program; and

(2) The State has given the Regional Administrator written notice, before total repayment was due, of its intent to repay by installments.

(b) *Annual State share determination.* HCFA determines whether the amount to be repaid exceeds 2½ percent of the annual State share as follows:

(1) If the Medicaid program is ongoing, HCFA uses the annual *estimated* State share of Medicaid expenditures. This is the sum of the estimated State shares for four consecutive quarters, beginning with the quarter in which the first installment is to be paid, as shown on the State's latest HCFA-25 form.

(2) If the Medicaid program has been terminated by Federal law or by the State, HCFA uses the *actual* State share. The actual State share is that shown on the State's Statement of Expenditures reports for the last four quarters before the program was terminated.

(c) *Repayment amounts, schedules, and procedures*—(1) *Repayment amount.* The repayment amount may not include any amount previously approved for installment repayment.

(2) *Repayment schedule.* The number of quarters allowed for repayment is determined on the basis of the ratio of the repayment amount to the annual State share of Medicaid expenditures. The higher the ratio of the total repayment amount is to the annual State share, the greater the number of quarters allowed, as follows:

Total repayment amount as percentage of State share of annual expenditures for Medicaid	Number of quarters to make repayment
2.5 pct. or less	1
Greater than 2.5, but not greater than 5	2
Greater than 5, but not greater than 7.5	3
Greater than 7.5, but not greater than 10	4
Greater than 10, but not greater than 15	5
Greater than 15, but not greater than 20	6
Greater than 20, but not greater than 25	7
Greater than 25, but not greater than 30	8
Greater than 30, but not greater than 47.5	9
Greater than 47.5, but not greater than 65	10
Greater than 65, but not greater than 82.5	11
Greater than 82.5, but not greater than 100	12

(3) *Quarterly repayment amounts.* The quarterly repayment amounts for each of the quarters in the repayment schedule may not be less than the following percentages of the estimated State share of the annual expenditures for Medicaid:

For each of the following quarters	Repayment installment may not be less than these percentages
1 to 4	2.5
5 to 8	5.0
9 to 12	17.5

(4) *Extended schedule.* The repayment schedule may be extended beyond 12 quarterly installments if the total repayment amount exceeds 100% of the estimated State share of annual expenditures. In these circumstances, paragraph (c)(2) of this section is followed for repayment of the amount equal to 100 percent of the annual State share. The remaining amount of the repayment is in quarterly amounts equal to not less than 17.5 percent of the estimated State share of annual expenditures.

(5) *Repayment process.* Repayment is accomplished through adjustment in the quarterly grants over the period covered by the repayment schedule.

If the State chooses to repay amounts representing higher percentages during the early quarters, any corresponding reduction in required minimum percentages is applied first to the last scheduled payment, then to the next to the last payment, and so forth as neccessary.

(6) *Offsetting of retroactive claims.* The amount of a retroactive claim to be paid a State will be offset against any amounts to be, or already being, repaid by the State in installments. Under this provision, the State may choose to:

(i) Suspend payments until the retroactive claim due the State has, in fact, been offset; or

(ii) Continue payments until the reduced amount of its debt (remaining after the offset), has been paid in full.

This second option would result in a shorter payment period.

A retroactive claim for the purpose of this regulation is a claim applicable to any period ending 12 months or more before the beginning of the quarter in which HCFA would pay that claim.

Subpart D—Hearings on Conformity of State Medicaid Plan and Practice to Federal Requirements

§ 430.60 Scope.

(a) This subpart sets forth the rules for hearings to States that appeal a decision to disapprove State plan material (under § 430.18) or to withhold Federal funds (under § 430.35), because the State plan or State practice in the Medicaid program is not in compliance with Federal requirements.

(b) Nothing in this subpart is intended to preclude or limit negotiations between HCFA and the State, whether before, during, or after the hearing to resolve the issues that are, or otherwise would be, considered at the hearing. Such negotiations and resolution of issues are not part of the hearing, and are not governed by the rules in this subpart except as expressly provided.

§ 430.62 Records to be public.

All pleadings, correspondence, exhibits, transcripts of testimony, exceptions, briefs, decisions, and other documents filed in the docket in any proceeding may be inspected and copied in the office of the HCFA Docket Clerk. Inquiries may be made to the Docket Clerk, Hearing Staff, Bureau of Eligibility, Reimbursment and Coverage, 300 East High Rise, 6325 Security Boulevard, Baltimore, Maryland, 21207. Telephone: (301) 594-8261.

§ 430.63 Filing and service of papers.

(a) *Filing.* All papers in the proceedings are filed with the HCFA Docket Clerk, in an original and two copies. Originals only of exhibits and transcripts of testimony need be filed.

(b) *Service.* All papers in the proceedings are served on all parties by personal delivery or by mail. Service on the party's designated attorney is considered service upon the party.

§ 430.64 Suspension of rules.

Upon notice to all parties, the Administrator or the presiding officer may modify or waive any rule in this subpart upon determination that no party will be unduly prejudiced and the ends of justice will thereby be served.

§ 430.66 Designation of presiding officer for hearing.

(a) The presiding officer at a hearing is the Administrator or his designee.

(b) The designation of the presiding officer is in writing. A copy of the designation is served on all parties.

§ 430.70 Notice of hearing or opportunity for hearing.

The Administrator mails the State a notice of hearing or opportunity for hearing that—

(a) Specifies the time and place for the hearing;

(b) Specifies the issues that will be considered;

(c) Identifies the presiding officer; and

(d) Is published in the FEDERAL REGISTER.

§ 430.72 Time and place of hearing.

(a) *Time.* The hearing is scheduled not less than 30 nor more than 60 days after the date of notice to the State. The scheduled date may be changed by written agreement between HCFA and the State.

(b) *Place.* The hearing is conducted in the city in which the HCFA regional office is located or in another place fixed by the presiding officer in light of the circumstances of the case, with due regard for the convenience and necessity of the parties or their representatives.

§ 430.74 Issues at hearing.

The list of issues specified in the notice of hearing may be augmented or reduced as provided in this section.

(a) *Additional issues.* (1) Before a hearing under § 430.35, the Administrator may send written notice to the State listing additional issues to be considered at the hearing. That notice is published in the FEDERAL REGISTER.

(2) If the notice of additional issues is furnished to the State less than 20 days before the scheduled hearing date, postponement is granted if requested by the State or any other party. The new date may be 20 days after the date of the notice, or a later date agreed to by the presiding officer.

(b) *New or modified issues.* If, as a result of negotiations between HCFA and the State, the submittal of plan amendment, a change in the State program, or other actions by the State, any issue is resolved in whole or in part, but new or modified issues are presented, as specified by the presiding officer, the hearing proceeds on the new or modified issues.

(c) *Issues removed from consideration*—(1) *Basis for removal.* If at any time before, during, or after the hearing, the presiding officer finds that the State has come into compliance with Federal requirements on any issue or part of an issue, he or she removes the appropriate issue or part of an issue from consideration. If all issues are removed, the hearing is terminated.

(2) *Notice to parties.* Before removing any issue or part of an issue from consideration, the presiding officer provides all parties other than HCFA and the State with—

(i) A statement of the intent to remove and the reasons for removal; and

(ii) A copy of the proposed State plan provision on which HCFA and the State have agreed.

(3) *Opportunity for written comment.* The notified parties have 15 days to submit, for consideration by the presiding officer, and for the record, their views as to, or any information bearing upon, the merits of the proposed plan provision and the merits of the reasons for removing the issue from consideration.

(d) *Remaining issues.* The issues considered at the hearing are limited to those issues of which the State is notified as provided in § 430.70 and paragraph (a) of this section, and new or modified issues described in paragraph (b) of this section. They do not include issues or parts of issues removed in accordance with paragraph (c) of this section.

§ 430.76 Parties to the hearing.

(a) *HCFA and the State.* HCFA and the State are parties to the hearing.

(b) *Other individuals*—(1) *Basis for participation.* Other individuals or groups may be recognized as parties if the issues to be considered at the hearing have caused them injury and their interest is within the zone of interests to be protected by the governing Federal statute.

(2) *Petition for participation.* Any individual or group wishing to participate as a party must, within 15 days after notice of hearing is published in the FEDERAL REGISTER, file with the HCFA Docket Clerk, a petition that concisely states—

(i) Petitioner's interest in the proceeding;

(ii) Who will appear for petitioner;

(iii) The issues on which petitioner wishes to participate; and

(iv) Whether petitioner intends to present witnesses.

The petitioner must also serve a copy of the petition on each party of record at that time.

(3) *Comments on petition.* Any party may, within 5 days of receipt of the copy of the petition, file comments on it.

(4) *Action on petition.* (i) The presiding officer promptly determines whether each petitioner has the requisite interest in the proceedings and approves or denies participation accordingly.

(ii) If petitions are made by more than one individual or group with common interests, the presiding officer may—

(A) Request all those petitioners to designate a single representative; or

(B) Recognize one or more of those petitioners to represent all of them.

(iii) The presiding officer gives each petitioner written notice of the decision and, if the decision is to deny, briefly states the grounds for denial.

(c) *Amicus curiae (friend of the court)*—(1) *Petition for participation.* Any person or organization that wishes to participate as amicus curiae must, before the hearing begins, file with the HCFA Docket Clerk, a petition that concisely states—

(i) The petitioners' interest in the hearing;

(ii) Who will represent the petitioner; and

(iii) The issues on which the petitioner intends to present argument.

(2) *Action on amicus curiae petition.* The presiding officer may grant the petition if he or she finds that the petitioner has a legitimate interest in the proceedings, that such participation will not unduly delay the outcome and may contribute materially to the proper disposition of the issues.

(3) *Nature of amicus participation.* An amicus curiae is not a party to the hearing but may participate by—

(i) Submitting a written statement of position to the presiding officer before the beginning of the hearing;

(ii) Presenting a brief oral statement at the hearing, at the point in the proceedings specified by the presiding officer; and

(iii) Submitting a brief or written statement when the parties submit briefs.

The amicus curiae must serve copies of any briefs or written statements on all parties.

§ 430.80 Authority of the presiding officer.

(a) The presiding officer has the duty to conduct a fair hearing, to avoid delay, maintain order, and make a record of the proceedings. He or she has the authority necessary to accomplish those ends, including but not limited to authority to take the following actions:

(1) Change the date, time, and place of the hearing after due notice to the parties. This includes authority to postpone or adjourn the hearing in whole or in part. In a hearing on disapproval of a State plan, or State plan amendments, changes in the date of the hearing are subject to the time limits imposed by section 1116(a)(2) of the Act.

(2) Hold conferences to settle or simplify the issues, or to consider other matters that may aid in the expeditious disposition of the issues.

(3) Regulate participation of parties and amici curiae and require parties and amici curiae to state their position with respect to the various issues in the proceeding.

(4) Administer oaths and affirmations.

(5) Rule on motions and other procedural items, including issuance of protective orders or other relief to a party against whom discovery is sought.

(6) Regulate the course of the hearing and conduct of counsel.

(7) Examine witnesses.

(8) Receive, rule on, exclude or limit evidence or discovery.

(9) Fix the time for filing motions, petitions, briefs, or other items.

(10) If the presiding officer is the Administrator, make a final decision.

(11) If the presiding officer is a designee of the Administrator, certify the entire record including recommended findings and proposed decision to the Administrator.

(12) Take any action authorized by the rules in this subpart or in conformance with the provisions of 5 U.S.C. 551 through 559.

(b) The presiding officer does not have authority to compel by subpoena the production of witnesses, papers, or other evidence.

(c) If the presiding officer is a designee of the Administrator, his or her authority pertains to the issues of compliance by a State with Federal requirements, and does not extend to the question of whether, in case of any noncompliance, Federal payments will be denied in respect to the entire State plan or only for certain categories under, or parts of, the State plan affected by the noncompliance.

§ 430.83 Rights of parties.

All parties may:

(a) Appear by counsel or other authorized representative, in all hearing proceedings.

(b) Participate in any prehearing conference held by the presiding officer.

(c) Agree to stipulations as to facts which will be made a part of the record.

(d) Make opening statements at the hearing.

(e) Present relevant evidence on the issues at the hearing.

(f) Present witnesses who then must be available for cross examination by all other parties.

(g) Present oral arguments at the hearing.

(h) Submit written briefs, proposed findings of fact, and proposed conclusions of law, after the hearing.

§ 430.86 Discovery.

HCFA and any party named in the notice issued under § 430.70 has the right to conduct discovery (including depositions) against opposing parties. Rules 26-37 of the Federal Rules of Civil Procedures apply to such proceedings; there will be no fixed rule on priority of discovery. Upon written motion, the presiding officer promptly rules upon any objection to discovery action initiated under this section. The presiding officer also has the power to grant a protective order or relief to any party against whom discovery is sought and to restrict or control discovery so as to prevent undue delay in the conduct of the hearing. Upon the failure of any party to make discovery, the presiding officer may issue any order and impose any sanction (other than contempt orders) authorized by Rule 37 of the Federal Rules of Civil Procedure.

§ 430.88 Evidence.

(a) *Evidentiary purpose.* The hearing is directed to receiving factual evidence and expert opinion testimony related to the issues involved in the proceeding. Argument is not received in evidence. It must be presented in statements, memoranda, or briefs, as determined by the presiding officer. Brief opening statements, concerning the party's position and what he or she intends to prove, may be made at hearings.

(b) *Testimony.* Testimony is given orally under oath or affirmation by witnesses at the hearing. Witnesses are available at the hearing for cross-examination by all parties.

(c) *Stipulations and exhibits.* Two or more parties may agree to stipulations of fact. Those stipulations, and any exhibit proposed by any party, are exchanged before the hearing if the presiding officer so requires.

(d) *Rules of evidence.* (1) Technical rules of evidence do not apply to hearings conducted under this subpart. However, rules or principles designed to ensure production of the most credible evidence available and to subject testimony to test by cross-examination are applied by the presiding officer when reasonably necessary.

(2) A witness may be cross-examined on any matter material to the proceeding without regard to the scope of his or her direct examination.

(3) The presiding officer may exclude irrelevant, immaterial, or unduly repetitious evidence.

(4) All documents and other evidence offered or taken for the record are open to examination by the parties and an opportunity is given to refute facts and arguments advanced on either side of the issues.

§ 430.90 Exclusion from hearing for misconduct.

The presiding officer may immediately exclude from the hearing any person who—

(a) Uses disrespectful, disorderly, or contumacious language or engages in contemptuous behavior;

(b) Refuses to comply with directions; or

(c) Uses dilatory tactics.

§ 430.92 Unsponsored written material.

Letters expressing views or urging action and other unsponsored written material regarding matters in issue in a hearing are placed in the correspondence section of the docket of the proceeding. These data are not considered part of the evidence or record in the hearing.

§ 430.94 Official transcript.

(a) *Filing.* The official transcripts of testimony, together with any stipulations, briefs, or memoranda of law, are filed with HCFA.

(b) *Availability of transcripts.* HCFA designates an official reporter for each hearing. Transcripts of testimony in hearings may be obtained from the official reporter by the parties and the public at rates not in excess of the maximum rates fixed by the contract between HCFA and the reporter.

(c) *Correction of transcript.* Upon notice to all parties, the presiding officer may authorize corrections that affect substantive matters in the transcript.

§ 430.96 Record for decision.

The transcript of testimony, exhibits, and all papers and requests filed in the proceedings, except the correspondence section of the docket, including rulings and any recommended or initial decision constitute the exclusive record for decision.

§ 430.100 Posthearing briefs.

The presiding officer fixes the time for filing posthearing briefs, which may contain proposed findings of fact and conclusions of law. The presiding officer may also permit reply briefs.

§ 430.102 Decisions following hearing.

(a) *Administrator presides.* If the presiding officer is the Administrator, he or she issues the hearing decision within 60 days after expiration of the period for submission of posthearing briefs.

(b) *Administrator's designee presides.* If the presiding officer is other than the Administrator, the procedure is as follows:

(1) Upon expiration of the period allowed for submission of posthearing briefs, the presiding officer certifies the entire record, including his or her recommended findings and proposed decision, to the Administrator. The Administrator serves a copy of the recommended findings and proposed decision upon all parties and amici, if any.

(2) Any party may, within 20 days, file with the Administrator exceptions to the recommended findings and proposed decision and a supporting brief or statement.

(3) The Administrator reviews the recommended decision and, within 60 days of its issuance, issues his or her own decision.

(c) *Effect of Administrator's decision.* The decision of the Administrator under this section is the final decision of the Secretary and constitutes "final agency action" within the meaning of 5 U.S.C. 704 and a "final determination" within the meaning of section 1116(a)(3) of the Act and § 430.38. The Administrator's decision is promptly served on all parties and amici.

§ 430.104 Decisions that affect FFP.

(a) *Scope of decisions.* If the Administrator concludes that withholding of FFP is necessary because a State is out of compliance with Federal requirements, in accordance with § 430.35, the decision also specifies—

(1) Whether no further payments will be made to the State or whether payments will be limited to parts of the program not affected by the noncompliance; and

(2) The effective date of the decision to withhold.

(b) *Consultation.* The Administrator may ask the parties for recommendations or briefs or may hold conferences of the parties on the question of further payments to the State.

(c) *Effective date of decision.* The effective date of a decision to withhold Federal funds will not be earlier than the date of the Administrator's decision and will not be later than the first day of the next calendar quarter. The provisions of this section may not be waived under § 430.64.

EFFECTIVE DATE NOTE: At 53 FR 36571, Sept. 21, 1988, Part 430 was revised, effective October 21, 1988. For the convenience of the user, the superseded text is set forth below.

PART 430—GRANTS TO STATES FOR MEDICAL ASSISTANCE PROGRAMS

Subpart A—Introduction; Definitions

AUTHORITY: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

§ 430.0 Introduction to Subchapter C.

(a) *Program description.* Title XIX of the Social Security Act, enacted in 1965, authorizes Federal grants to States for medical assistance to low-income persons who are age 65 or over, blind, disabled, or members of families with dependent children. The program is jointly financed by the Federal and State governments and administered by States. Within broad Federal rules, each State decides eligible groups, types and range of services, payment levels for services, and administrative and operating procedures. Payments for services are made directly by the State to the individuals or entities that furnish the services.

(b) *Federal regulations.* (1) The regulations in Subchapter C set forth State plan requirements, standards, procedures, and conditions for obtaining Federal matching. Each part (or subpart or section) in the subchapter describes the specific statutory basis for the regulation. However, where the basis is the Secretary's general authority to issue regulations for any program under the Act (section 1102 of the Act), or his general authority to prescribe State plan requirements needed for proper and efficient administration of the plan (section 1902(a)(4)), those statutory provisions are simply cited without further description.

(2) Other regulations applicable to State Medicaid programs include:

(i) 5 CFR Part 900, Subpart F. Administration of the Standards for a Merit System of Personnel Administration; and

(ii) The following HHS Regulations in 45 CFR Subtitle A:

Part 16—Department Grant Appeals Process.

Part 74—Administration of Grants.

Part 80—Nondiscrimination Under Programs Receiving Federal Assistance Through the Department of Health and Human Services: Effectuation of Title VI of the Civil Rights Act of 1964.

Part 81—Practice and Procedure for Hearings Under 45 CFR Part 80.

Part 84—Nondiscrimination on the Basis of Handicap in Programs and Activities Receiving or Benefiting From Federal Financial Assistance.

(3) Regulations in 45 CFR Parts 201, 204, 205, and 213 also apply to the Medicaid program, to the extent specified.

[43 FR 45187, Sept. 29, 1978, as amended at 45 FR 24882, Apr. 11, 1980; 51 FR 36227, Oct. 9, 1986; 52 FR 28657, July 31, 1987]

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431.804 Disallowance of Federal financial participation for erroneous State payments (effective January 1, 1984).

AUTHORITY: Sec. 1102 of the Social Security Act, (42 U.S.C. 1302).

SOURCE: 43 FR 45188, Sept. 29, 1978, unless otherwise noted.

§ 431.1 Purpose.

This part establishes State plan requirements for the designation, organization, and general administrative activities of a State agency responsible for operating the State Medicaid program, directly or through supervision of local administering agencies.

Subpart A—Single State Agency

§ 431.10 Single State agency.

(a) *Basis and purpose.* This section implements section 1902(a)(5) of the Act, which provides for designation of a single State agency for the Medicaid program.

(b) *Designation and certification.* A State plan must—

(1) Specify a single State agency established or designated to administer or supervise the administration of the plan; and

(2) Include a certification by the State Attorney General, citing the legal authority for the single State agency to—

(i) Administer or supervise the administration of the plan; and

(ii) Make rules and regulations that it follows in administering the plan or that are binding upon local agencies that administer the plan.

(c) *Determination of eligibility.* (1) The plan must specify whether the agency that determines eligibility for families and for individuals under 21 is—

(i) The Medicaid agency; or

(ii) The single State agency for the financial assistance program under title IV-A (in the 50 States or the District of Columbia), or under title I or XVI (AABD), in Guam, Puerto Rico, or the Virgin Islands.

(2) The plan must specify whether the agency that determines eligibility for the aged, blind, or disabled is—

(i) The Medicaid agency;

(ii) The single State agency for the financial assistance program under title IV-A (in the 50 States or the District of Columbia) or under title I or XVI (AABD), in Guam, Puerto Rico, or the Virgin Islands; or

(iii) The Federal agency administering the supplemental security income program under title XVI (SSI). In this case, the plan must also specify whether the Medicaid agency or the title IV-A agency determines eligibility for any groups whose eligibility is not determined by the Federal agency.

(d) *Agreement with Federal or State agencies.* The plan must provide for written agreements between the Medicaid agency and the Federal or other State agencies that determine eligibility for Medicaid, stating the relationships and respective responsibilities of the agencies.

(e) *Authority of the single State agency.* In order for an agency to qualify as the Medicaid agency—

(1) The agency must not delegate, to other than its own officials, authority to—

(i) Exercise administrative discretion in the administration or supervision of the plan, or

(ii) Issue policies, rules, and regulations on program matters.

(2) The authority of the agency must not be impaired if any of its rules, regulations, or decisions are subject to review, clearance, or similar action by other offices or agencies of the State.

(3) If other State or local agencies or offices perform services for the Medicaid agency, they must not have the authority to change or disapprove any administrative decision of that agency, or otherwise substitute their judgment for that of the Medicaid agency with respect to the application of policies, rules, and regulations issued by the Medicaid agency.

[44 FR 17930, Mar. 23, 1979]

§ 431.11 Organization for administration.

(a) *Basis and purpose.* This section, based on section 1902(a)(4) of the Act, prescribes the general organization and staffing requirements for the Medicaid agency and the State plan.

(b) *Medical assistance unit.* A State plan must provide for a medical assistance unit within the Medicaid agency, staffed with a program director and other appropriate personnel who participate in the development, analysis, and evaluation of the Medicaid program.

(c) *Description of organization.* (1) The plan must include—

(i) A description of the organization and functions of the Medicaid agency and an organization chart;

(ii) A description of the organization and functions of the medical assistance unit and an organization chart; and

(iii) A description of the kinds and number of professional medical personnel and supporting staff used in the administration of the plan and their responsibilities.

(d) *Eligibility determined by other agencies.* If eligibility is determined by State agencies other than the Medicaid agency or by local agencies under the supervision of other State agencies, the plan must include a description of the staff designated by those other agencies and the functions they perform in carrying out their responsibility.

[44 FR 17931, Mar. 23, 1979]

§ 431.12 Medical care advisory committee.

(a) *Basis and purpose.* This section, based on section 1902(a)(4) of the Act, prescribes State plan requirements for establishment of a committee to advise the Medicaid agency about health and medical care services.

(b) *State plan requirement.* A State plan must provide for a medical care advisory committee meeting the requirements of this section to advise the Medicaid agency director about health and medical care services.

(c) *Appointment of members.* The agency director, or a higher State authority, must appoint members to the advisory committee on a rotating and continuous basis.

(d) *Committee membership.* The committee must include—

(1) Board-certified physicians and other representatives of the health professions who are familiar with the medical needs of low-income population groups and with the resources available and required for their care;

(2) Members of consumers' groups, including Medicaid recipients, and consumer organizations such as labor unions, cooperatives, consumer-sponsored prepaid group practice plans, and others; and

(3) The director of the public welfare department or the public health department, whichever does not head the Medicaid agency.

(e) *Committee participation.* The committee must have opportunity for participation in policy development and program administration, including furthering the participation of recipient members in the agency program.

(f) *Committee staff assistance and financial help.* The agency must provide the committee with—

(1) Staff assistance from the agency and independent technical assistance as needed to enable it to make effective recommendations; and

(2) Financial arrangements, if necessary, to make possible the participation of recipient members.

(g) *Federal financial participation.* FFP is available at 50 percent in expenditures for the committee's activities.

§ 431.15 Methods of administration.

A State plan must provide for methods of administration that are found by the Secretary to be necessary for the proper and efficient operation of the plan.

(Sec. 1902(a)(4) of the Act)

[44 FR 17931, Mar. 23, 1979]

§ 431.16 Reports.

A State plan must provide that the Medicaid agency will—

(a) Submit all reports required by the Secretary;

(b) Follow the Secretary's instructions with regard to the form and content of those reports; and

(c) Comply with any provisions that the Secretary finds necessary to verify and assure the correctness of the reports.

[44 FR 17931, Mar. 23, 1979]

§ 431.17 Maintenance of records.

(a) *Basis and purpose.* This section, based on section 1902(a)(4) of the Act, prescribes the kinds of records a Medicaid agency must maintain, the retention period, and the conditions under which microfilm copies may be substituted for original records.

(b) *Content of records.* A State plan must provide that the Medicaid agency will maintain or supervise the maintenance of the records necessary for the proper and efficient operation of the plan. The records must include—

(1) Individual records on each applicant and recipient that contain information on—

(i) Date of application;

(ii) Date of and basis for disposition;

(iii) Facts essential to determination of initial and continuing eligibility;

(iv) Provision of medical assistance;

(v) Basis for discontinuing assistance;

(vi) The disposition of income and eligibility verification information received under §§ 435.940 through 435.960 of this subchapter; and

(2) Statistical, fiscal, and other records necessary for reporting and accountability as required by the Secretary.

(c) *Retention of records.* The plan must provide that the records required under paragraph (b) of this section will be retained for the periods required by the Secretary.

(d) *Conditions for optional use of microfilm copies.* The agency may substitute certified microfilm copies for the originals of substantiating documents required for Federal audit and review, if the conditions in paragraphs (d)(1) through (4) of this section are met.

(1) The agency must make a study of its record storage and must show that the use of microfilm is efficient and economical.

(2) The microfilm system must not hinder the agency's supervision and control of the Medicaid program.

(3) The microfilm system must—

(i) Enable the State to audit the propriety of expenditures for which FFP is claimed; and

(ii) Enable the HHS Audit Agency and HCFA to properly discharge their respective responsibilities for reviewing the manner in which the Medicaid program is being administered.

(4) The agency must obtain approval from the HCFA regional office indicating—

(i) The system meets the conditions of paragraphs (d)(2) and (3) of this section; and

(ii) The microfilming procedures are reliable and are supported by an adequate retrieval system.

[44 FR 17931, Mar. 23, 1979, as amended at 51 FR 7210, Feb. 28, 1986]

§ 431.18 Availability of agency program manuals.

(a) *Basis and purpose.* This section, based on section 1902(a)(4) of the Act, prescribes State plan requirements for facilitating access to Medicaid rules and policies by individuals outside the State Medicaid agency.

(b) *State plan requirements.* A State plan must provide that the Medicaid agency meets the requirements of paragraphs (c) through (g) of this section.

(c) *Availability in agency offices.* (1) The agency must maintain, in all its offices, copies of its current rules and policies that affect the public, including those that govern eligibility, provision of medical assistance, covered services, and recipient rights and responsibilities.

(2) These documents must be available upon request for review, study, and reproduction by individuals during regular working hours of the agency.

(d) *Availability through other entities.* The agency must provide copies of its current rules and policies to—

(1) Public and university libraries;

(2) The local or district offices of the Bureau of Indian Affairs;

(3) Welfare and legal services offices; and

(4) Other entities that—

(i) Request the material in order to make it accessible to the public;

(ii) Are centrally located and accessible to a substantial number of the recipient population they serve; and

(iii) Agree to accept responsibility for filing all amendments or changes forwarded by the agency.

(e) *Availability in relation to fair hearings.* The agency must make available to an applicant or recipient, or his representative, a copy of the specific policy materials necessary—

(1) To determine whether to request a fair hearing; or

(2) To prepare for a fair hearing.

(f) *Availability for other purposes.* The agency must establish rules for making program policy materials available to individuals who request them for other purposes.

(g) *Charges for reproduction.* The agency must make copies of its program policy materials available without charge or at a charge related to the cost of reproduction.

[44 FR 17931, Mar. 23, 1979]

Subpart B—Administrative Requirements: General Program Services

§ 431.50 Statewide operation.

(a) *Basis and purpose.* This section implements section 1902(a)(1) of the Act, which requires a State plan to be in effect throughout the State, and section 1915, which permits certain exceptions.

(b) *State plan requirements.* A State plan must provide that the following requirements will be met:

(1) The plan will be in operation statewide through a system of local offices, under equitable standards for assistance and administration that are mandatory throughout the State.

(2) If administered by political subdivisions of the State, the plan will be mandatory on those subdivisions.

(3) The agency will assure that the plan is continuously in operation in all local offices or agencies through—

(i) Methods for informing staff of State policies, standards, procedures, and instructions;

(ii) Systematic planned examination and evaluation of operations in local offices by regularly assigned State staff who make regular visits; and

(iii) Reports, controls, or other methods.

(c) *Exceptions.* The requirements of paragraph (b) of this section do not apply with respect to:

(1) Services offered by comprehensive health services organizations (see § 440.250(g) of this subchapter);

(2) Services offered by rural health clinics (see § 440.20(b));

(3) Arrangements under § 431.54(d) to purchase medical devices or laboratory and x-ray services (as defined in § 440.30);

(4) Lock-in or lock-out restrictions under § 431.54 (e) and (f); and

(5) Services offered under a waiver with respect to home and community based services (§ 440.180).

[44 FR 17931, Mar. 23, 1979, as amended at 46 FR 48539, Oct. 1, 1981; 46 FR 54744, Nov. 4, 1981]

§ 431.51 Free choice of providers.

(a) *Basis and purpose.* This section implements section 1902(a)(23) of the Act, which provides that recipients may obtain services from any qualified Medicaid provider, and section 1915 of the Act, which provides that a State shall not be found out of compliance with section 1902(a)(23) solely by reason of certain specified allowable restrictions of this free choice (see paragraph (c) of this section and § 431.54) and which authorizes the Secretary to waive the requirements of section 1902(a)(23), and other provisions of the Act, in certain circumstances (see § 431.55).

(b) *State plan requirement.* Except as provided in paragraph (c) of this section, a State plan (except in Puerto Rico, the Virgin Islands, and Guam) must provide that any recipient may obtain Medicaid services from any institution, agency, pharmacy, person, or organization that is qualified to perform the services, including an organization that provides these services or arranges for their availability on a prepayment basis.

(c) *Limitations on applicability.* Paragraph (b) of this section does not prohibit the agency from—

(1) Establishing the fees it will pay providers for Medicaid services;

(2) Setting reasonable standards relating to the qualifications of providers; or

(3) Restricting recipients' free choice of providers in accordance with one or more of the exceptions provided for under § 431.54, or under a waiver as provided for under § 431.55.

(d) *Certification requirement.* If a State implements a project under one of the exceptions allowed under § 431.54 (d), (e) or (f), it must certify to HCFA that the statutory safeguards and requirements for an exception under section 1915(a) of the Act are met. The certification must be submitted by the end of the quarter in which the State implements the project, except that the certification must be submitted prior to instituting the project in the case of an exception under § 431.54(d), for which the Secretary must make certain findings before the project may be initiated.

[43 FR 45188, Sept. 29, 1978, as amended at 48 FR 23221, May 24, 1983]

§ 431.52 Payments for services furnished out of State.

(a) *Basis and purpose.* This section implements:

(1) Section 1902(a)(16) of the Act, which authorizes the Secretary to prescribe State plan requirements for furnishing Medicaid to State residents who are absent from the State; and

(2) Section 1902(a)(10)(A) of the Act, which requires a State plan to provide for Medicaid for all individuals receiving assistance under the State's title IV-E plan.

(b) *Payment for services.* A State plan must provide that the State will furnish Medicaid to:

(1) A recipient who is a resident of the State while that recipient is in another State, to the same extent that Medicaid is furnished to residents in the State, when:

(i) Medical services are needed because of a medical emergency;

(ii) Medical services are needed because the recipient's health would be endangered if he were required to travel to his State of residence;

(iii) The State determines, on the basis of medical advice, that the needed medical services, or necessary supplementary resources, are more readily available in the other State; or

(iv) It is general practice for recipients in a particular locality to use medical resources in another State; and

(2) A child for whom the State makes adoption assistance or foster care maintenance payments under title IV-E of the Act.

(c) *Cooperation among States.* The plan must provide that the State will establish procedures to facilitate the furnishing of medical services to individuals who are present in the State and are eligible for Medicaid under another State's plan.

[43 FR 45188, Sept. 29, 1978, as amended at 47 FR 28655, July 1, 1982]

§ 431.53 Assurance of transportation.

A State plan must—

(a) Specify that the Medicaid agency will assure necessary transportation for recipients to and from providers; and

(b) Describe the methods that will be used to meet this requirement.

(Sec. 1902(a)(4) of the Act)

§ 431.54 Exceptions to certain State plan requirements.

(a) *Basis and purpose.* This section implements section 1915(a) of the Act, which provides that a State shall not be deemed to be out of compliance with the requirements of sections 1902(a) (1), (10), or (23) of the Act solely by reason of certain specified allowable exceptions, as set forth in this section.

(b) *Services on a prepayment basis.* If the Medicaid agency contracts on a prepayment basis with an organization that provides services additional to those offered under the State plan, the agency may restrict the provision of the additional services to recipients who live in the area served by the organization and wish to obtain services from it.

(c) *Rural health clinic services.* The State Medicaid agency may require in its State plan that payment will be made for rural health clinic services only if those services are provided by a rural health clinic.

(d) *Competitive bidding or other arrangements.* The Medicaid agency may enter into arrangements to purchase medical devices or laboratory and X-ray tests (as defined in § 440.30) through a competitive bidding process or otherwise, if the State assures in the certification required under § 431.51(d), and the Secretary finds, that adequate services or devices are available to recipients under the arrangements. In addition, the State must certify and the Secretary must find that:

(1) Laboratory services purchased under such arrangements are provided through independent laboratories, hospital laboratories (in-or-outpatient) that provide services for non-hospital patients, and physician laboratories that process at least 100 specimens during any calendar year from other physicians. These laboratories must meet the requirements of Part 405, Subpart J or Part 405, Subpart M of this chapter. Laboratories requiring an interstate license under 42 CFR Part 74 must be licensed by HCFA or receive an exemption from the licensing requirement by the College of Ameri-

can Pathologists. (Hospital and physician laboratories may participate in competitive bidding only with regard to services to non-hospital patients and other physicians' patients, respectively.)

(2) Any laboratory from which a State purchases services under this section has no more than 75 percent of its charges based on services to beneficiaries or recipients of Medicaid or Medicare.

(e) *Lock-in of recipients who overutilize Medicaid services.* If a Medicaid agency finds that a recipient has utilized Medicaid services or items at a frequency or amount that is not medically necessary, as determined in accordance with utilization guidelines established by the State, the agency may restrict that recipient for a reasonable period of time to obtain Medicaid services or items from designated providers only. The agency may impose these restrictions provided that:

(1) The agency gives the recipient notice and opportunity for a hearing (in accordance with procedures established by the agency) before such restrictions are imposed.

(2) The agency assures that the recipient has reasonable access (taking into account geographic location and reasonable travel time) to Medicaid services of adequate quality.

(3) The restrictions will not apply to emergency services furnished to the recipient.

(f) *Lock-out of providers.* If a Medicaid agency finds that a provider of items or services under the State plan has abused the Medicaid program, the agency may restrict the provider, through suspension or otherwise, from participating in the Medicaid program for a reasonable period of time. The agency may impose these restrictions subject to the following limitations:

(1) Before imposing any restriction, the agency gives the provider notice and opportunity for a hearing, in accordance with procedures established by the agency.

(2) The agency must find, before restricting a provider, that in a significant number or proportion of cases, the provider has:

(i) Provided Medicaid items or services at a frequency or amount not medically necessary, as determined in accordance with utilization guidelines established by the agency; or

(ii) Provided Medicaid items or services of a quality that does not meet professionally recognized standards of health care.

(3) The agency must—

(i) Notify HCFA when it imposes a restriction; and

(ii) Give a general notice to the public of the restriction and its duration.

(4) The agency may not impose restrictions which would result in denying recipients reasonable access (taking into account geographic location and reasonable travel time) to Medicaid services of adequate quality, including emergency services.

[43 FR 45188, Sept. 29, 1978, as amended at 48 FR 23221, May 24, 1983]

§ 431.55 Waiver of other Medicaid requirements.

(a) *Basis and purpose.* This section implements section 1915(b) of the Act, as added by section 2175 of Pub. L. 97-35 and as amended by section 137 of Pub. L. 97-248, which authorizes the Secretary to waive the requirements of sections 1902 and 1903(m) (as permitted under paragraph (h) of this section) of the Act to the extent he or she finds proposed improvements in the provision of services under Medicaid to be cost-effective, efficient, and consistent with the objectives of the Medicaid program. This section also implements sections 1915 (d), (e), and (f) of the Act, which govern how such waivers are to be approved, continued, monitored, and terminated. Additionally, paragraph (g) of this section implements section 1916(a)(3) and (b)(3) of the Act, which authorizes the Secretary to waive the requirement in those sections that cost-sharing amounts be nominal.

(b) *General requirements.* (1) HCFA will consider only waiver requests submitted to HCFA by or through the Governor, State cabinet members responsible for State Medicaid agency activities, director of the State Medicaid agency, or by someone with the authority to submit waiver requests on behalf of the director.

(2) In applying for a waiver to implement an approvable project under paragraph (c), (d), (e), or (f) of this section, a Medicaid agency must document in the waiver request and maintain data regarding:

(i) The cost-effectiveness of the project;

(ii) The effect on recipients regarding access to care and quality of services; and

(iii) The projected impact of the program.

(3) No waiver under this section may be granted for a period longer than 2 years, unless the agency requests a continuation of the waiver.

(4) HCFA will monitor the implementation of waivers granted under this section to assure that requirements for such waivers are being met.

(i) Where monitoring demonstrates evidence that the agency is not in compliance with the requirements for a waiver under this section, the agency shall be given notice and opportunity for a hearing.

(ii) If, after a hearing, HCFA finds an agency to be out of compliance with the requirements of a waiver, that waiver shall be terminated, and the agency shall be given a specified date by which it must demonstrate that it meets the applicable requirements of sections 1902 and 1903(m) of the Act.

(c) *Case-management system.* Waivers of appropriate requirements of sections 1902 and 1903(m) (as permitted under paragraph (h) of this section) of the Act may be authorized for a State to implement a primary care case-management system or specialty physician services arrangements which restricts the provider from or through whom a recipient can obtain medical care services (other than in emergency circumstances) provided that those restrictions do not substantially impair access to such services of adequate quality where medically necessary.

(1) Under a primary care case-management system the agency assures that a specific person or persons or agency will be responsible for locating, coordinating, and monitoring all primary care or primary care and other medical care and rehabilitative services on behalf of a recipient.

(2) A specialty physician services arrangement allows States to restrict recipients of specialty services to designated providers of such services, even in the absence of a primary care case-management system.

(d) *Locality as central broker.* Waivers of appropriate requirements of sections 1902 and 1903(m) (as permitted under paragraph (h) of this section) of the Act may be authorized for a State to allow a locality to act as a central broker in assisting individuals (eligible for medical assistance under this title) in selecting among competing health care plans. States must ensure that access to medically necessary services of adequate quality is not substantially impaired.

(1) A locality is any defined jurisdiction, e.g., district, town, city, borough, county, parish, or State.

(2) A locality may utilize any agency or agent, public or private, profit or nonprofit, to act on its behalf in carrying out its central broker function.

(e) *Sharing of cost savings.* Waivers of appropriate requirements of sections 1902 and 1903(m) (as permitted under paragraph (h) of this section) of the Act may be authorized for a State to share (through provision of additional services) with recipients of medical assistance under the State plan cost savings resulting from use by the recipient of more cost-effective medical care. Additional services include those offered by plans selected by recipients, as well as those offered expressly by a State as an inducement for recipients to participate in a primary care case-management system, a "competing health care plan", or other arrangements that result in more cost effective medical care.

(f) *Restriction of freedom of choice.* Waiver of appropriate requirements of sections 1902 and 1903(m) (as permitted under paragraph (h) of this section) of the Act may be authorized for States to restrict recipients to obtaining services from (or through) qualified providers or practitioners that meet, accept, and comply with the State reimbursement, quality and utilization standards specified in the State's waiver request.

(1) An agency may qualify for such a waiver only if——

(i) Its applicable State standards are consistent with access, quality and efficient and economic provision of covered care and services;

(ii) The restrictions it imposes do not discriminate among classes of providers on grounds unrelated to their demonstrated effectiveness and efficiency in providing those services; and

(iii) The restrictions it imposes do not apply in emergency circumstances.

(2) Demonstrated effectiveness and efficiency refers to reducing costs or slowing the rate of increase and maximizing outputs or outcomes per unit of cost.

(3) The provisions of this section do not apply to recipients residing at a long-term care facility when a restriction is imposed unless the State arranges for reasonable and adequate recipient transfer.

(g) *Cost sharing requirement.* Beginning October 1, 1982, under sections 1916(a)(3) and (b)(3), the Secretary may permit by waiver, copayments of up to double the nominal amount, as described in § 447.54, to be imposed on nonemergency services furnished in a hospital emergency room.

(1) Nonemergency services are those services that do not meet the definition of emergency services at § 447.53(b)(4).

(2) In order for a waiver to be approved under this provision, the State must establish to the satisfaction of HCFA, that alternative sources of nonemergency, outpatient services are available and accessible to eligible individuals.

(3) Although, in accordance with paragraph (b)(2) of this section, a waiver will generally be granted for a 2 year duration, HCFA will re-evaluate approved waivers if the State increases the nominal copayment amounts in effect when the waiver was approved.

(4) A waiver approved under this provision cannot apply to services furnished before the waiver was granted or to services furnished before October 1, 1982.

(h) *Section 1903(m) waivers.* Appropriate requirements under section 1903(m) of the Act are waived only where a waiver of those requirements was granted by the Secretary and the arrangements were in place before August 10, 1982. Such a waiver may remain in effect only for the period for which it was initially approved.

[48 FR 23222, May 24, 1983, as amended at 50 FR 23013, May 30, 1985]

§ 431.56 Special waiver provisions applicable to American Samoa.

(a) *Basis and purpose.* This section implements section 1902(j) of the Act, which provides for waiver of requirements, in the case of American Samoa.

(b) *Waiver provisions.* American Samoa may request, and HCFA may approve, a waiver of any of the title XIX requirements except the following:

(1) The Federal medical assistance percentage specified in section 1903 of the Act and § 433.10(b) of this chapter.

(2) The limit imposed by section 1108(c) of the Act on the amount of Federal funds payable to American Samoa for care and services that meet the section 1905(a) definition for Medicaid assistance.

(3) The requirement that payment be made only with respect to expenditure made by American Samoa for care and services that meet the section 1905(a) definition of medical assistance.

[51 FR 41350, Nov. 14, 1986; 52 FR 4499, Feb. 12, 1987]

Subpart C—Administrative Requirements: Provider Relations

§ 431.105 Consultation to medical facilities.

(a) *Basis and purpose.* This section implements section 1902(a)(24) of the Act, which requires that the State plan provide for consultative services by State agencies to certain institutions furnishing Medicaid services.

(b) *State plan requirements.* A State plan must provide that health agencies and other appropriate State agencies furnish consultative services to hospitals, nursing homes, home health agencies, clinics, and laboratories in order to assist these facilities to—

(1) Qualify for payments under the maternal and child health and crip-

pled children's program (title V of the Act), Medicaid or Medicare;

(2) Establish and maintain fiscal records necessary for the proper and efficient administration of the Act; and

(3) Provide information needed to determine payments due under the Act for services furnished to recipients.

(c) *State plan option: Consultation to other facilities.* The plan may provide that health agencies and other appropriate State agencies furnish consultation to other types of facilities if those facilities are specified in the plan and provide medical care to individuals receiving services under the programs specified in paragraph (b) of this section.

§ 431.107 Required provider agreement.

(a) *Basis and purpose.* This section sets forth State plan requirements, based on sections 1902(a)(4) and 1902(a)(27) of the Act, that relate to the keeping of records and the furnishing of information by all providers of services (including individual practitioners and groups of practitioners).

(b) *Agreements.* A State plan must provide for an agreement between the Medicaid agency and each provider furnishing services under the plan in which the provider agrees to:

(1) Keep any records necessary to disclose the extent of services the provider furnishes to recipients;

(2) On requests, furnish to the Medicaid agency, the Secretary, or the State Medicaid fraud control unit (if such a unit has been approved by the Secretary under § 455.300 of this chapter), any information maintained under paragraph (b)(1) of this section and any information regarding payments claimed by the provider for furnishing services under the plan; and

(3) Comply with the disclosure requirements specified in Part 455, Subpart B of this chapter.

[44 FR 41644, July 17, 1979]

§ 431.110 Participation by Indian Health Service facilities.

(a) *Basis.* This section is based on section 1902(a)(4) of the Act, proper and efficient administration; 1902(a)(23), free choice of provider; and 1911, reimbursement of Indian Health Service facilities.

(b) *State plan requirements.* A State plan must provide that an Indian Health Service facility meeting State requirements for Medicaid participation must be accepted as a Medicaid provider on the same basis as any other qualified provider. However, when State licensure is normally required, the facility need not obtain a license but must meet all applicable standards for licensure. In determining whether a facility meets these standards, a Medicaid agency or State licensing authority may not take into account an absence of licensure of any staff member of the facility.

§ 431.115 Disclosure of survey information and provider or contractor evaluation.

(a) *Basis and purpose.* This section implements—

(1) Section 1902(a)(36) of the Act, which requires a State plan to provide that the State survey agency will make publicly available the findings from surveys of health care facilities, laboratories, agencies, clinics, or organizations; and

(2) Section 1106(d) of the Act, which places certain restrictions on the Medicaid agency's disclosure of contractor and provider evaluations.

(b) *Definition of State survey agency.* The State survey agency referred to in this section means the agency specified under section 1902(a)(9) of the Act as responsible for establishing and maintaining health standards for private or public institutions in which Medicaid recipients may receive services.

(c) *State plan requirement.* A State plan must provide that the requirements of this section are met.

(d) *Disclosure procedure.* The Medicaid agency must have a procedure for disclosing pertinent findings obtained from surveys made by the State survey agency to determine if a health care facility, laboratory, agency, clinic or health care organization meets the requirements for participation in the Medicaid program.

(e) *Documents subject to disclosure.* Documents subject to disclosure include—

(1) Survey reports, except for Joint Commission on the Accreditation of Hospitals reports prohibited from disclosure under § 422.426(b)(2) of this chapter;

(2) Official notifications of findings based on survey reports:

(3) Pertinent parts of written documents furnished by the health care provider to the survey agency that relate to the reports and findings; and

(4) Ownership and contract information as specified in § 455.104 of this subchapter.

(f) *Availability for inspection and copy of statements listing deficiencies.* The disclosure procedure must provide that the State survey agency will—

(1) Make statements of deficiencies based on the survey reports available for inspection and copying in both the public assistance office and the Social Security Administration district office serving the area where the provider is located; and

(2) Submit to the Regional Medicaid Director, through the Medicaid agency, a plan for making those findings available in other public assistance offices in standard metropolitan statistical areas where this information would be helpful to persons likely to use the health care provider's services.

(g) *When documents must be made available.* The disclosure procedure must provide that the State survey agency will—

(1) Retain in the survey agency office and make available upon request survey reports and current and accurate ownership information; and

(2) Make available survey reports, findings, and deficiency statements immediately upon determining that a health care provider is eligible to begin or continue participation in the Medicaid program, or within 90 days after completion of the survey, whichever occurs first.

(h) *Evaluation reports on providers and contractors.* (1) If the Secretary sends the following reports to the Medicaid agency, the agency must meet the requirements of paragraphs (h) (2) and (3) of this section in releasing them:

(i) Individual contractor performance reviews and other formal performance evaluations of carriers, intermediaries, and State agencies, including the reports of followup reviews;

(ii) Comparative performance evaluations of those contractors, including comparisons of either overall performance or of any particular aspect of contractor operations; and

(iii) Program validation survey reports and other formal performance evaluations of providers, including the reports of followup reviews.

(2) The agency must not make the reports public until—

(i) The contractor or provider has had a reasonable opportunity, not to exceed 30 days, to comment on them; and

(ii) Those comments have been incorporated in the report.

(3) The agency must ensure that the reports contain no identification of individual patients, individual health care practitioners or other individuals.

[43 FR 45188, Sept. 29, 1978, as amended at 44 FR 41644, July 17, 1979]

Subpart D—Appeals Process for SNF's and ICF's

SOURCE: 44 FR 9753, Feb. 15, 1979, unless otherwise noted.

§ 431.151 Scope and applicability.

This subpart specifies the appeal procedures the State must make available to a skilled nursing facility (SNF) or intermediate care facility (ICF) for which the State denies, terminates, or fails to renew certification or a provider agreement for the Medicaid program.

§ 431.152 State plan requirements.

The State plan must provide for appeals procedures that, as a minimum, satisfy the requirements of §§ 431.153 through 431.155.

§ 431.153 Evidentiary hearing.

(a) Except as specified in paragraph (d) of this section, any SNF or ICF whose certification or provider agreement is denied, terminated, or not renewed must be given an opportunity for a full evidentiary hearing on the denial, termination or nonrenewal.

(b) If the facility requests a hearing, it must be completed either before the effective date of the denial, termination or nonrenewal or within 120 days after that date.

(c) The hearing must, at a minimum, include—

(1) Timely written notice to the facility of the basis for the decision and disclosure of the evidence on which the decision is taken;

(2) An opportunity for the facility to appear before an impartial decision maker to refute the basis for the decision;

(3) An opportunity for the facility to be represented by counsel or another representative;

(4) An opportunity for the facility or its representatives to be heard in person, to call witnesses, and to present documentary evidence;

(5) An opportunity for the facility to cross-examine witnesses; and

(6) A written decision by the impartial decision maker, setting forth the reasons for the decision and the evidence upon which the decision is based.

(d) If a SNF is participating, or seeking to participate, in both Medicare and Medicaid, and if the basis for the State's denial, termination or nonrenewal of participation in Medicaid is also a basis for denial, termination or nonrenewal of participation in Medicare, the State must advise the facility that—

(1) The facility is entitled to the review procedures specified for Medicare facilities in Part 498 of this chapter, in lieu of the procedures specified in this subpart; and

(2) A final decision entered under the Medicare review procedures will be binding for purposes of Medicaid participation.

[44 FR 9753, Feb. 15, 1979, as amended at 52 FR 22454, June 12, 1987]

§ 431.154 Informal reconsideration.

(a) If the State decides to provide the opportunity for an evidentiary hearing required by § 431.153 only after the effective date of a denial, termination or nonrenewal, the State must offer the facility an informal reconsideration, to be completed before the effective date.

(b) The informal reconsideration must, at a minimum, include—

(1) Written notice to the facility of the denial, termination or nonrenewal and the findings upon which it was based;

(2) A reasonable opportunity for the facility to refute those findings in writing, and

(3) A written affirmation or reversal of the denial, termination, or nonrenewal

Subpart E—Fair Hearings for Applicants and Recipients

SOURCE: 44 FR 17932, Mar. 29, 1979, unless otherwise noted.

GENERAL PROVISIONS

§ 431.200 Basis and purpose.

This subpart implements section 1902(a)(3) of the Act, which requires that a State plan provide an opportunity for a fair hearing to any person whose claim for assistance is denied or not acted upon promptly. This subpart also prescribes procedures for an opportunity for hearing if the Medicaid agency takes action to suspend, terminate, or reduce services.

§ 431.201 Definitions.

For purposes of this subpart:

"Action" means a termination, suspension, or reduction of Medicaid eligibility or covered services.

"Date of action" means the intended date on which a termination, suspension, or reduction becomes effective.

"De novo hearing" means a hearing that starts over from the beginning.

"Evidentiary hearing" means a hearing conducted so that evidence may be presented.

"Notice" means a written statement that meets the requirements of § 431.210.

"Request for a hearing" means a clear expression by the applicant or recipient, or his authorized representative, that he wants the opportunity to present his case to a reviewing authority.

§ 431.202 State plan requirements.

A State plan must provide that the requirements of §§ 431.205 through 431.246 of this subpart are met.

§ 431.205 Provision of hearing system.

(a) The Medicaid agency must be responsible for maintaining a hearing system that meets the requirements of this subpart.

(b) The State's hearing system must provide for—

(1) A hearing before the agency; or

(2) An evidentiary hearing at the local level, with a right of appeal to a State agency hearing.

(c) The agency may offer local hearings in some political subdivisions and not in others.

(d) The hearing system must meet the due process standards set forth in *Goldberg v. Kelly*, 397 U.S. 245 (1970), and any additional standards specified in this subpart.

§ 431.206 Informing applicants and recipients.

(a) The agency must issue and publicize its hearing procedures.

(b) The agency must, at the time specified in paragraph (c) of this section, inform every applicant or recipient in writing—

(1) Of his right to a hearing;

(2) Of the method by which he may obtain a hearing; and

(3) That he may represent himself or use legal counsel, a relative, a friend, or other spokesman.

(c) The agency must provide the information required in paragraph (b) of this section—

(1) At the time that the individual applies for Medicaid; and

(2) At the time of any action affecting his claim.

NOTICE

§ 431.210 Content of notice.

A notice required under § 431.206(c)(2) of this subpart must contain—

(a) A statement of what action the agency intends to take;

(b) The reasons for the intended action;

(c) The specific regulations that support, or the change in Federal or State law that requires, the action;

(d) An explanation of—

(1) The individual's right to request an evidentiary hearing if one is available, or a State agency hearing; or

(2) In cases of an action based on a change in law, the circumstances under which a hearing will be granted; and

(e) An explanation of the circumstances under which Medicaid is continued if a hearing is requested.

§ 431.211 Advance notice.

The State or local agency must mail a notice at least 10 days before the date of action, except as permitted under §§ 431.213 and 431.214 of this subpart.

§ 431.213 Exceptions from advance notice.

The agency may mail a notice not later than the date of action if—

(a) The agency has factual information confirming the death of a recipient;

(b) The agency receives a clear written statement signed by a recipient that—

(1) He no longer wishes services; or

(2) Gives information that requires termination or reduction of services and indicates that he understands that this must be the result of supplying that information;

(c) The recipient has been admitted to an institution where he is ineligible under the plan for further services;

(d) The recipient's whereabouts are unknown and the post office returns agency mail directed to him indicating no forwarding address (See § 431.231 (d) of this subpart for procedure if the recipient's whereabouts become known);

(e) The agency establishes the fact that the recipient has been accepted for Medicaid services by another local jurisdiction, State, territory, or commonwealth; or

(f) A change in the level of medical care is prescribed by the recipient's physician.

§ 431.214 Notice in cases of probable fraud.

The agency may shorten the period of advance notice to 5 days before the date of action if—

(a) The agency has facts indicating that action should be taken because of probable fraud by the recipient; and

(b) The facts have been verified, if possible, through secondary sources.

RIGHT TO HEARING

§ 431.220 When a hearing is required.

(a) The agency must grant an opportunity for a hearing to:

(1) Any applicant who requests it because his claim for services is denied or is not acted upon with reasonable promptness; and

(2) Any recipient who requests it because he believes the agency has taken an action erroneously.

(b) The agency need not grant a hearing if the sole issue is a Federal or State law requiring an automatic change adversely affecting some or all recipients.

§ 431.221 Request for hearing.

(a) The agency may require that a request for a hearing be in writing.

(b) The agency may not limit or interfere with the applicant's or recipient's freedom to make a request for a hearing.

(c) The agency may assist the applicant or recipient in submitting and processing his request.

(d) The agency must allow the applicant or recipient a reasonable time, not to exceed 90 days from the date that notice of action is mailed, to request a hearings.

§ 431.222 Group hearings.

The agency—

(a) May respond to a series of individual requests for hearing by conducting a single group hearing;

(b) May consolidate hearings only in cases in which the sole issue involved is one of Federal or State law or policy;

(c) Must follow the policies of this subpart and its own policies governing hearings in all group hearings; and

(d) Must permit each person to present his own case or be represented by his authorized representative.

§ 431.223 Denial or dismissal of request for a hearing.

The agency may deny or dismiss a request for a hearing if—

(a) The applicant or recipient withdraws the request in writing; or

(b) The applicant or recipient fails to appear at a scheduled hearing without good cause.

PROCEDURES

§ 431.230 Maintaining services.

(a) If the agency mails the 10-day or 5-day notice as required under § 431.211 or § 431.214 of this subpart, and the recipient requests a hearing before the date of action, the agency may not terminate or reduce services until a decision is rendered after the hearing unless—

(1) It is determined at the hearing that the sole issue is one of Federal or State law or policy; and

(2) The agency promptly informs the recipient in writing that services are to be terminated or reduced pending the hearing decision.

(b) If the agency's action is sustained by the hearing decision, the agency may institute recovery procedures against the applicant or recipient to recoup the cost of any services furnished the recipient, to the extent they were furnished solely by reason of this section.

[44 FR 17932, Mar. 29, 1979, as amended at 45 FR 24882, Apr. 11, 1980]

§ 431.231 Reinstatement of services.

(a) The agency may reinstate services if a recipient requests a hearing not more than 10 days after the date of action.

(b) The reinstated services must continue until a hearing decision unless, at the hearing, it is determined that the sole issue is one of Federal or State law or policy.

(c) The agency must reinstate and continue services until a decision is rendered after a hearing if—

(1) Action is taken without the advance notice required under § 431.211 or § 431.214 of this subpart;

(2) The recipient requests a hearing within 10 days of the mailing of the notice of action; and

(3) The agency determines that the action resulted from other than the application of Federal or State law or policy.

(d) If a recipient's whereabouts are unknown, as indicated by the return of unforwardable agency mail directed to him, any discontinued services must be reinstated if his whereabouts become known during the time he is eligible for services.

§ 431.232 Adverse decision of local evidentiary hearing.

If the decision of a local evidentiary hearing is adverse to the applicant or recipient, the agency must—

(a) Inform the applicant or recipient of the decision;

(b) Inform the applicant or recipient that he has the right to appeal the decision to the State agency, in writing, within 15 days of the mailing of the notice of the adverse decision;

(c) Inform the applicant or recipient of his right to request that his appeal be a *de novo* hearing; and

(d) Discontinue services after the adverse decision.

§ 431.233 State agency hearing after adverse decision of local evidentiary hearing.

(a) Unless the applicant or recipient specifically requests a *de novo* hearing, the State agency hearing may consist of a review by the agency hearing officer of the record of the local evidentiary hearing to determine whether the decision of the local hearing officer was supported by substantial evidence in the record.

(b) A person who participates in the local decision being appealed may not participate in the State agency hearing decision.

§ 431.240 Conducting the hearing.

(a) All hearings must be conducted—

(1) At a reasonable time, date, and place;

(2) Only after adequate written notice of the hearing; and

(3) By one or more impartial officials or other individuals who have not been directly involved in the initial determination of the action in question.

(b) If the hearing involves medical issues such as those concerning a diagnosis, an examining physician's report, or a medical review team's decision, and if the hearing officer considers it necessary to have a medical assessment other than that of the individual involved in making the original decision, such a medical assessment must be obtained at agency expense and made part of the record.

§ 431.241 Matters to be considered at the hearing.

The hearing must cover—

(a) Agency action or failure to act with reasonable promptness on a claim for services, including both initial and subsequent decisions regarding eligibility; and

(b) Agency decisions regarding changes in the type or amount of services.

§ 431.242 Procedural rights of the applicant or recipient.

The applicant or recipient, or his representative, must be given an opportunity to—

(a) Examine at a reasonable time before the date of the hearing and during the hearing:

(1) The content of the applicant's or recipient's case file; and

(2) All documents and records to be used by the State or local agency at the hearing;

(b) Bring witnesses;

(c) Establish all pertinent facts and circumstances;

(d) Present an argument without undue interference; and

(e) Question or refute any testimony or evidence, including opportunity to confront and cross-examine adverse witnesses.

§ 431.243 Parties in cases involving an eligibility determination.

If the hearing involves an issue of eligibility and the Medicaid agency is not responsible for eligibility determinations, the agency that is responsible for determining eligibility must participate in the hearing.

§ 431.244 Hearing decisions.

(a) Hearing recommendations or decisions must be based exclusively on evidence introduced at the hearing.

(b) The record must consist only of—

(1) The transcript or recording of testimony and exhibits, or an official report containing the substance of what happened at the hearing;

(2) All papers and requests filed in the proceeding; and

(3) The recommendation or decision of the hearing officer.

(c) The applicant or recipient must have access to the record at a convenient place and time.

(d) In any evidentiary hearing, the decision must be a written one that—

(1) Summarizes the facts; and

(2) Identifies the regulations supporting the decision.

(e) In a *de novo* hearing, the decision must—

(1) Specify the reasons for the decision; and

(2) Identify the supporting evidence and regulations.

(f) The agency must take final administrative action within 90 days from the date of the request for a hearing.

(g) The public must have access to all agency hearing decisions, subject to the requirements of Subpart F of this part for safeguarding of information.

§ 431.245 Notifying the applicant or recipient of a State agency decision.

The agency must notify the applicant or recipient in writing of—

(a) The decision; and

(b) His right to request a State agency hearing or seek judicial review, to the extent that either is available to him.

§ 431.246 Corrective action.

The agency must promptly make corrective payments, retroactive to the date an incorrect action was taken, if—

(a) The hearing decision is favorable to the applicant or recipient; or

(b) The agency decides in the applicant's or recipient's favor before the hearing.

FEDERAL FINANCIAL PARTICIPATION

§ 431.250 Federal financial participation.

FFP is available in expenditures for—

(a) Payments for services continued pending a hearing decision;

(b) Payments made—

(1) To carry out hearing decisions; and

(2) For services provided within the scope of the Federal Medicaid program and made under a court order.

(c) Payments made to take corrective action prior to a hearing;

(d) Payments made to extend the benefit of a hearing decision or court order to individuals in the same situation as those directly affected by the decision or order;

(e) Retroactive payments under paragraphs (b), (c), and (d) of this section in accordance with applicable Federal policies on corrective payments; and

(f) Administrative costs incurred by the agency for—

(1) Transportation for the applicant or recipient, his representative, and witnesses to and from the hearing;

(2) Meeting other expenses of the applicant or recipient in connection with the hearing; and

(3) Carrying out the hearing procedures, including expenses of obtaining the additional medical assessment specified in § 431.240 of this subpart.

[44 FR 17932, Mar. 29, 1979, as amended at 45 FR 24882, Apr. 11, 1980]

Subpart F—Safeguarding Information on Applicants and Recipients

SOURCE: 44 FR 17934, Mar. 29, 1979, unless otherwise noted.

§ 431.300 Basis and purpose.

(a) Section 1902(a)(7) of the Act requires that a State plan must provide safeguards that restrict the use or disclosure of information concerning applicants and recipients to purposes directly connected with the administration of the plan. This subpart specifies State plan requirements, the types of information to be safeguarded, the conditions for release of safeguarded information, and restrictions on the distribution of other information.

(b) Section 1137 of the Act, which requires agencies to exchange information in order to verify the income and eligibility of applicants and recipients (see § 435.940ff), requires State agencies to have adequate safeguards to assure that—

(1) Information exchanged by the State agencies is made available only to the extent necessary to assist in the valid administrative needs of the program receiving the information, and information received under section 6103(l) of the Internal Revenue Code of 1954 is exchanged only with agencies authorized to receive that information under that section of the Code; and

(2) The information is adequately stored and processed so that it is protected against unauthorized disclosure for other purposes.

[51 FR 7210, Feb. 28, 1986]

§ 431.301 State plan requirements.

A State plan must provide, under a State statute that imposes legal sanctions, safeguards meeting the requirements of this subpart that restrict the use or disclosure of information concerning applicants and recipients to purposes directly connected with the administration of the plan.

§ 431.302 Purposes directly related to State plan administration.

Purposes directly related to plan administration include—

(a) Establishing eligibility;

(b) Determining the amount of medical assistance;

(c) Providing services for recipients; and

(d) Conducting or assisting an investigation, prosecution, or civil or criminal proceeding related to the administration of the plan.

§ 431.303 State authority for safeguarding information.

The Medicaid agency must have authority to implement and enforce the provisions specified in this subpart for safeguarding information about applicants and recipients.

§ 431.304 Publicizing safeguarding requirements.

(a) The agency must publicize provisions governing the confidential nature of information about applicants and recipients, including the legal sanctions imposed for improper disclosure and use.

(b) The agency must provide copies of these provisions to applicants and recipients and to other persons and agencies to whom information is disclosed.

§ 431.305 Types of information to be safeguarded.

(a) The agency must have criteria that govern the types of information about applicants and recipients that are safeguarded.

(b) This information must include at least—

(1) Names and addresses;

(2) Medical services provided;

(3) Social and economic conditions or circumstances;

(4) Agency evaluation of personal information;

(5) Medical data, including diagnosis and past history of disease or disability; and

(6) Any information received for verifying income eligibility and amount of medical assistance payments (see § 435.940ff). Income information received from SSA or the Internal Revenue Service must be safeguarded according to the requirements of the agency that furnished the data.

(7) Any information received in connection with the identification of legally liable third party resources under § 433.138 of this chapter.

[44 FR 17934, Mar. 29, 1979, as amended at 51 FR 7210, Feb. 28, 1986; 52 FR 5975, Feb. 27, 1987]

§ 431.306 Release of information.

(a) The agency must have criteria specifying the conditions for release and use of information about applicants and recipients.

(b) Access to information concerning applicants or recipients must be restricted to persons or agency representatives who are subject to standards of confidentiality that are comparable to those of the agency.

(c) The agency must not publish names of applicants or recipients.

(d) The agency must obtain permission from a family or individual, whenever possible, before responding to a request for information from an outside source, unless the information is to be used to verify income, eligibility and the amount of medical assistance payment under section 1137 of this Act and §§ 435.940 through 435.965 of this chapter.

If, because of an emergency situation, time does not permit obtaining consent before release, the agency must notify the family or individual immediately after supplying the information.

(e) The agency's policies must apply to all requests for information from outside sources, including governmental bodies, the courts, or law enforcement officials.

(f) If a court issues a subpoena for a case record or for any agency representative to testify concerning an applicant or recipient, the agency must inform the court of the applicable statutory provisions, policies, and regulations restricting disclosure of information.

(g) Before requesting information from, or releasing information to, other agencies to verify income, eligibility and the amount of assistance under §§ 435.940 through 435.965 of this chapter, the agency must execute data exchange agreements with those agencies, as specified in § 435.945(f).

(h) Before requesting information from, or releasing information to, other agencies to identify legally liable third party resources under § 433.138(d) of this chapter, the agency must execute data exchanges agreements, as specified in § 433.138(h)(2) of this chapter.

[44 FR 17934, Mar. 29, 1979, as amended at 51 FR 7210, Feb. 28, 1986; 52 FR 5975, Feb. 27, 1987]

§ 431.307 Distribution of information materials.

(a) All materials distributed to applicants, recipients, or medical providers must—

(1) Directly relate to the administration of the Medicaid program;

(2) Have no politicial implications;

(3) Contain the names only of individuals directly connected with the administration of the plan; and

(4) Identify those individuals only in their official capacity with the State or local agency.

(b) The agency must not distribute materials such as "holiday" greetings, general public announcements, voting information, and alien registration notices.

(c) The agency may distribute materials directly related to the health and welfare of applicants and recipients, such as announcements of free medical examinations, availability of surplus food, and consumer protection information.

Subparts G—L [Reserved]

Subpart M—Relations With Other Agencies

§ 431.610 Relations with standard-setting and survey agencies.

(a) *Basis and purpose.* This section implements—

(1) Section 1902(a)(9) of the Act, concerning the designation of State authorities to be responsible for establishing and maintaining health and other standards for institutions participating in Medicaid; and

(2) Section 1902(a)(33) of the Act, concerning the designation of the State licensing agency to be responsible for determining whether institutions and agencies meet requirements for participation in the State's Medicaid program.

(b) *Designated agency responsible for health standards.* A State plan must designate, as the State authority responsible for establishing and maintaining health standards for private or public institutions that provide services to Medicaid recipients, the same State agency that is used by the Secretary to determine qualifications of institutions and suppliers of services to participate in Medicare (see 42 CFR 405.1902). The requirement for establishing and maintaining standards does not apply with respect to Christian Science sanitoria operated, or listed and certified, by the First

Church of Christ Scientist, Boston, Mass.

(c) *Designated agency responsible for standards other than health standards.* The plan must designate the Medicaid agency or other appropriate State authority or authorities to be responsible for establishing and maintaining standards, other than those relating to health, for private or public institutions that provide services to Medicaid recipients.

(d) *Description and retention of standards.* (1) The plan must describe the standards established under paragraphs (b) and (c) of this section.

(2) The plan must provide that the Medicaid agency keeps these standards on file and makes them available to the Administrator upon request.

(e) *Designation of survey agency.* The plan must provide that—

(1) The agency designated in paragraph (b) of this section, or another State agency responsible for licensing health institutions in the State, determines for the Medicaid agency if institutions and agencies meet the requirements for participation in the Medicaid program; and

(2) The agency staff making the determination under paragraph (e)(1) of this section is the same staff responsible for making similar determinations for institutions or agencies participating under Medicare.

(f) *Written agreement required.* The plan must provide for a written agreement (or formal written intra-agency arrangement) between the Medicaid agency and the survey agency designated under paragraph (e) of this section, covering the activities of the survey agency in carrying out its responsibilities. The agreement must specify that—

(1) Federal requirements and the forms, methods and procedures that the Administrator designates will be used to determine provider eligibility and certification under Medicaid;

(2) Inspectors surveying the premises of a provider will—

(i) Complete inspection reports;

(ii) Note on completed reports whether or not each requirement for which an inspection is made is satisfied; and

(iii) Document deficiencies in reports;

(3) The survey agency will keep on file all information and reports used in determining whether participating facilities meet Federal requirements; and

(4) The survey agency will make the information and reports required under paragraph (f)(3) of this section readily accessible to HHS and the Medicaid agency as necessary—

(i) For meeting other requirements under the plan; and

(ii) For purposes consistent with the Medicaid agency's effective administration of the program.

(g) *Responsibilities of survey agency.* The plan must provide that, in certifying skilled nursing and intermediate care facilities, the survey agency designated under paragraph (e) of this section will—

(1) Review and evaluate the following information as it relates to health and safety requirements:

(i) Medical and independent professional review team reports obtained under Part 456 of this subchapter.

(ii) Statements from facility payroll records that show the average number and types of personnel, in full-time equivalents, on each shift during at least one week, selected by the team to occur irregularly, in each quarter;

(2) Take necessary action to achieve compliance or to withdraw certification; and

(3) Have qualified personnel perform on-site inspections—

(i) At least once during each certification period or more frequently if there is a compliance question; and

(ii) For intermediate care facilities with deficiencies as described in §§ 442.112 and 442.113 of this subchapter, within 6 months after initial correction plan approval and every 6 months thereafter as required under those sections.

(h) *FFP for survey responsibilities.* (1) FFP is available in expenditures that the survey agency makes to carry out its survey and certification responsibilities under the agreement specified in paragraph (f) of this section.

(2) FFP is not available in any expenditures that the survey agency makes that are attributable to the

State's overall responsibilities under State law and regulations for establishing and maintaining standards.

[43 FR 45188, Sept. 29, 1978, as amended at 45 FR 24883, Apr. 11, 1980; 53 FR 20494, June 3, 1988]

EFFECTIVE DATE NOTE: At 53 FR 20494, June 3, 1988, § 431.610(f)(1) was amended by removing the word "standards" and adding in its place the word "requirements", effective October 3, 1988.

§ 431.615 Relations with State health and vocational rehabilitation agencies and title V grantees.

(a) *Basis and purpose.* This section implements section 1902(a)(11) and (22)(C) of the Act, by setting forth State plan requirements for arrangements and agreements between the Medicaid agency and—

(1) State health agencies;

(2) State vocational rehabilitation agencies; and

(3) Grantees under title V of the Act, Maternal and Child Health and Crippled Children's Services.

(b) *Definitions.* For purposes of this section—

"Title V grantee" means the agency, institution, or organization receiving Federal payments for part or all of the cost of any service program or project authorized by title V of the Act, including—

(1) Maternal and child health services;

(2) Crippled children's services;

(3) Maternal and infant care projects;

(4) Children and youth projects; and

(5) Projects for the dental health of children.

(c) *State plan requirements.* A state plan must—

(1) Describe cooperative arrangements with the State agencies that administer, or supervise the administration of, health services and vocational rehabilitation services designed to make maximum use of these services;

(2) Provide for arrangements with title V grantees, under which the Medicaid agency will utilize the grantee to furnish services that are included in the State plan;

(3) Provide that all arrangements under this section meet the requirements of paragraph (d) of this section; and

(4) Provide, if requested by the title V grantee in accordance with the arrangements made under this section, that the Medicaid agency reimburse the grantee or the provider for the cost of services furnished recipients by or through the grantee.

(d) *Content of arrangements.* The arrangements referred to in paragraph (c) must specify, as appropriate—

(1) The mutual objectives and responsibilities or each party to the arrangement;

(2) The services each party offers and in what circumstances;

(3) The cooperative and collaborative relationships at the State level;

(4) The kinds of services to be provided by local agencies; and

(5) Methods for—

(i) Early identification of individuals under 21 in need of medical or remedial services;

(ii) Reciprocal referrals;

(iii) Coordinating plans for health services provided or arranged for recipients;

(iv) Payment or reimbursement;

(v) Exchange of reports of services furnished to recipients;

(vi) Periodic review and joint planning for changes in the agreements;

(vii) Continuous liaison between the parties, including designation of State and local liaison staff; and

(viii) Joint evaluation of policies that affect the cooperative work of the parties.

(e) *Federal financial participation.* FFP is available in expenditures for Medicaid services provided to recipients through an arrangement under this section.

§ 431.620 Agreement with State mental health authority or mental institutions.

(a) *Basis and purpose.* This section implements section 1902(a)(20)(A) of the Act, for States offering Medicaid services in institutions for mental diseases for recipients aged 65 or older, by specifying the terms of the agreement those States must have with other State authorities and institutions. (See Part 441, Subpart C of this chapter for regulations implementing section 1902(a)(20) (B) and (C).)

(b) *Definition.* For purposes of this section, an "institution for mental diseases" means an institution primarily engaged in providing diagnosis, treatment, or care of persons with mental diseases. This includes medical attention, nursing care, and related services.

(c) *State plan requirement.* A State plan that includes Medicaid for persons aged 65 or older in institutions for mental diseases must provide that the Medicaid agency has in effect a written agreement with—

(1) The State authority or authorities concerned with mental diseases; and

(2) Any institution for mental diseases that is not under the jurisdiction of those State authorities, and that provides services under Medicaid to recipients aged 65 or older.

(d) *Provisions required in an agreement.* The agreement must specify the respective responsibilities of the agency and the authority or institution, including arrangements for—

(1) Joint planning between the parties to the agreement;

(2) Development of alternative methods of care;

(3) Immediate readmission to an institution when needed by a recipient who is in alternative care;

(4) Access by the agency to the institution, the recipient, and the recipient's records when necessary to carry out the agency's responsibilities;

(5) Recording, reporting, and exchanging medical and social information about recipients; and

(6) Other procedures needed to carry out the agreement.

[44 FR 17935, Mar. 23, 1979]

§ 431.625 Coordination of Medicaid with Medicare part B.

(a) *Basis and purpose.* (1) Section 1843(a) of the Act requires the Secretary to have entered into an agreement with any State that requested that agreement before January 1, 1970, or during calendar year 1981, under which the State could enroll certain Medicare-eligible recipients under Medicare Part B and agree to pay their premiums.

(2) Section 1902(a)(10) of the Act (in clause (II) following subparagraph (D)), allows the State to pay the premium, deductibles, cost sharing, and other charges for recipients enrolled under Medicare Part B without obligating itself to provide the range of Part B benefits to other recipients; and

(3) Section 1903 (a)(1) and (b) of the Act authorizes FFP for State payment of Medicare Part B premiums for certain recipients.

(4) This section—

(i) Specifies the exception, relating to Part B coverage, from the requirement to provide comparable services to all recipients; and

(ii) Prescribes FFP rules concerning State payment for Medicare premiums and for services that could have been covered under Medicare.

(5) Section 1902(a)(15) of the Act requires that if a State chooses to pay only a portion of deductibles, cost sharing or other charges for recipients enrolled under Medicare Part B, the portion that is to be paid by a Medicaid recipient must be reasonably related to the recipient's income and resources.

(b) *Exception from obligation to provide comparable services; State plan requirement.* (1) The State's payment of premiums, deductibles, cost sharing, or similar charges under Part B does not obligate it to provide the full range of Part B services to recipients not covered by Medicare.

(2) The State plan must specify this exception if it applies.

(c) *Effect of payment of premiums on State liability for cost sharing.* (1) State payment of Part B premiums on behalf of a Medicaid recipient does not obligate it to pay on the recipient's behalf the Part B deductible and coinsurance amounts for those Medicare Part B services not covered in the Medicaid State plan.

(2) If a State pays on a recipient's behalf any portion of the deductible or cost sharing amounts under Medicare Part B, the portion paid by a State must be reasonably related to the recipient's income and resources.

(d) *Federal financial participation: Medicare Part B premiums*—(1) *Basic rule.* Except as provided in paragraph (d)(2) of this section, FFP is not available in State expenditures for Medicare Part B premiums for Medicaid recipients unless the recipients receive money payments under title I, IV-A, X, XIV, XVI (AABD or SSI) of the Act, or State supplements as permitted under section 1616(a) of the Act, or as required by section 212 of Pub. L. 93-66.

(2) *Exception.* FFP is available in expenditures for Medicare Part B premiums for the following groups:

(i) AFDC families required to be covered under §§ 435.112 and 436.116 of this subchapter, those eligible for continued Medicaid coverage despite increased income from employment;

(ii) Recipients required to be covered under §§ 435.114, 435.134, and 436.112 of this subchapter, those eligible for continued Medicaid coverage despite increased income from monthly insurance benefits under title II of the Act;

(iii) Recipients required to be covered under § 435.135 of this subchapter, those eligible for continued Medicaid coverage despite increased income from cost-of-living increases under title II of the Act;

(iv) Recipients of foster care maintenance payments or adoption assistance payments who, under Part E of title IV of the Act are considered as receiving AFDC;

(v) Individuals required to be covered under § 435.120 of this chapter, that is, blind or disabled individuals who, under section 1619(b) of the Act, are considered to be receiving SSI;

(vi) Individuals who, in accordance with §§ 435.115 and 436.114 of this chapter are, for purposes of Medicaid eligibility, considered to be receiving AFDC. These are participants in a work supplementation program, or individuals denied AFDC because the payment would be less than $10;

(vii) Certain recipients of Veterans Administration pensions during the limited time they are, under section 310(b) of Pub. L. 96-272, considered as receiving SSI, mandatory State supplements, or AFDC;

(viii) Disabled children living at home to whom the State provides Medicaid under section 1902(e)(3) of the Act;

(ix) Individuals who become ineligible for AFDC because of the collection or increased collection of child or spousal support, but, in accordance with section 406(h) of the Act, remain eligible for Medicaid for four more months; and

(x) Individuals who become ineligible for AFDC because they are no longer eligible for the disregard of earnings of $30 or of $30 plus one-third of the remainder, but, in accordance with section 402(a)(37) of the Act, are considered as receiving AFDC for a period of 9 to 15 months.

(3) No FFP is available in State Medicaid expenditures that could have been paid for under Medicare Part B but were not because the person was not enrolled in Part B. This limit applies to all recipients eligible for enrollment under Part B, whether individually or through an agreement under section 1843(a) of the Act. However, FFP is available in expenditures required by §§ 435.914 and 436.901 of this subchapter for retroactive coverage of recipients.

[43 FR 45188, Sept. 29, 1978, as amended at 44 FR 17935, Mar. 23, 1979; 52 FR 47933, Dec. 17, 1987; 53 FR 657, Jan. 11, 1988]

§ 431.630 Coordination of Medicaid with PROs.

(a) The State plan may provide for the review of Medicaid services through a contract with a PRO designated under Part 462 of this chapter. Medicaid requirements for medical and utilization review are deemed to be met for those services or providers subject to review under the contract.

(b) The State plan must provide that the contract with the PRO—

(1) Meets the requirements of § 434.6(a) of this part;

(2) Includes a monitoring and evaluation plan by which the State ensures satisfactory performance by the PRO;

(3) Identifies the services and providers subject to PRO review;

(4) Ensures that the review activities performed by the PRO are not inconsistent with PRO review activities of Medicare services and includes a description of whether and to what extent PRO determinations will be considered conclusive for Medicaid payment purposes.

[50 FR 15327, Apr. 17, 1985]

Subpart N—State Programs for Licensing Nursing Home Administrators

§ 431.700 Basis and purpose.

This subpart implements sections 1903(a)(29) and 1908 of the Act which require that the State plan include a State program for licensing nursing home administrators.

§ 431.701 Definitions.

Unless otherwise indicated, the following definitions apply for purposes of this subpart:

"*Agency*" means the State agency responsible for licensing individual practitioners under the State's healing arts licensing act.

"*Board*" means an appointed State board established to carry out a State program for licensing administrators of nursing homes, in a State that does not have a healing arts licensing act or an agency as defined in this section.

"*Licensed*" means certified by a State agency or board as meeting all of the requirements for a licensed nursing home administrator specified in this subpart.

"*Nursing home*" means any institution, facility, or distinct part of a hospital that is licensed or formally recognized as meeting nursing home standards established under State law, or that is determined under § 431.704 to be included under the requirements of this subpart. The term does not include—

(a) A Christian Science sanatorium operated, or listed and certified, by the First Church of Christ, Scientist, Boston, Mass.; or

(b) A distinct part of a hospital, if the hospital meets the definition in § 440.10 or § 440.140 of this subchapter, and the distinct part is not licensed separately or formally approved as a nursing home by the State even though it is designated or certified as a skilled nursing facility.

"*Nursing home administrator*" means any person who is in charge of the general administration of a nursing home whether or not the person—

(a) Has an ownership interest in the home; or

(b) Shares his functions and duties with one or more other persons.

§ 431.702 State plan requirement.

A State plan must provide that the State has a program for licensing administrators of nursing homes that meets the requirements of §§ 431.703 through 431.713 of this subpart.

§ 431.703 Licensing requirement.

The State licensing program must provide that only nursing homes supervised by an administrator licensed in accordance with the requirements of this subpart may operate in the State.

§ 431.704 Nursing homes designated by other terms.

If a State licensing law does not use the term "nursing home," the HCFA Administrator will determine the term or terms equivalent to "nursing home" for purposes of applying the requirements of this subpart. To obtain this determination, the Medicaid agency must submit to the Regional Medicaid Director copies of current State laws that define institutional health care facilities for licensing purposes.

§ 431.705 Licensing authority.

(a) The State licensing program must provide for licensing of nursing home administrators by—

(1) The agency designated under the healing arts act of the State; or

(2) A State licensing board.

(b) The State agency or board must perform the functions and duties specified in §§ 431.707 through 431.713 and the board must meet the membership requirements specified in § 431.706 of this subpart.

§ 431.706 Composition of licensing board.

(a) The board must be composed of persons representing professions and institutions concerned with the care and treatment of chronically ill or infirm elderly patients. However—

(1) A majority of the board members may not be representative of a single profession or category of institution; and

(2) Members not representative of institutions may not have a direct financial interest in any nursing home.

(b) For purposes of this section, nursing home administrators are considered representatives of institutions.

§ 431.707 Standards.

(a) The agency or board must develop, impose, and enforce standards that must be met by individuals in order to be licensed as a nursing home administrator.

(b) The standards must be designed to insure that nursing home administrators are—

(1) Of good character;

(2) Otherwise suitable; and

(3) Qualified to serve because of training or experience in institutional administration.

§ 431.708 Procedures for applying standards.

The agency or board must develop and apply appropriate procedures and techniques, including examinations and investigations, for determining if a person meets the licensing standards.

§ 431.709 Issuance and revocation of license.

Except as provided in § 431.714 of this subpart, the agency or board must—

(a) Issue licenses to persons who meet the agency's or board's standards; and

(b) Revoke or suspend a license if the agency or board determines that the person holding the license substantially fails to meet the standards.

§ 431.710 Provisional licenses.

To fill a position of nursing home administrator that unexpectedly becomes vacant, the agency or board may issue one provisional license, for a single period not to exceed 6 months. The license may be issued to a person who does not meet all of the licensing requirements established under § 431.707 but who—

(a) Is of good character and otherwise suitable; and

(b) Meets any other standards established for provisional licensure by the agency or board.

§ 431.711 Compliance with standards.

The agency or board must establish and carry out procedures to insure that licensed administrators comply with the standards in this subpart when they serve as nursing home administrators.

§ 431.712 Failure to comply with standards.

The agency or board must investigate and act on all complaints it receives of violations of standards.

§ 431.713 Continuing study and investigation.

The agency or board must conduct a continuing study of nursing homes and administrators within the State to improve—

(a) Licensing standards; and

(b) The procedures and methods for enforcing the standards.

§ 431.714 Waivers.

The agency or board may waive any standards developed under § 431.707 of this subpart for any person who has served in the capacity of a nursing home administrator during all of the 3 calendar years immediately preceding the calendar year in which the State first meets the requirements in this subpart.

§ 431.715 Federal financial participation.

No FFP is available in expenditures by the licensing board for establishing and maintaining standards for the licensing of nursing home administrators.

Subpart O—[Reserved]

Subpart P—Quality Control

§ 431.800 Medicaid quality control (MQC) system.

(a) *Basis and purpose*—(1) *Basis*. This subpart implements the following sections of the Act, which establish requirements for State plans and for payment of Federal financial participation (FFP) to States:

1902(a)(4) Administrative methods for proper and efficient operation of the State plan.

1903(u) Limitation of FFP for erroneous medical assistance expenditures.

(2) *Purpose.* This section establishes State plan requirements for a Medicaid quality control system designed to reduce erroneous expenditures by monitoring eligibility determinations, and claims processing.

(b) *Definitions.* For purposes of this section—

"*Active case*" means an individual or family determined to be currently eligible for Medicaid.

"*Claims processing error*" means FFP has been claimed for a Medicaid payment that was made—

(1) For a service not authorized under the State plan;

(2) To a provider not certified for participation in the Medicaid program;

(3) For a service already paid for by Medicaid; or

(4) In an amount above the allowable reimbursement level for that service.

"*Eligibility error*" means that Medicaid coverage has been certified or payment has been made for a recipient under review who—

(1) Was ineligible when certified or when he received services under the State's plan; or

(2) Had not met recipient liability requirements when certified eligible for Medicaid; that is, he had not incurred medical expenses equal to the amount of this excess income over the State's financial eligibility level.

"*Negative case action*" means a Medicaid application that was denied or otherwise disposed of without a determination of eligibility (for instance, because the application was withdrawn or abandoned) or an individual or family for whom Medicaid eligibility was terminated.

"*State agency*" means either the State Medicaid agency, or a State agency that is responsible for determining eligibility for Medicaid.

(c) *State plan requirements.* (1) A State plan must provide for operating a Medicaid quality control (MQC) eligibility system that meets the requirements of paragraphs (d), (f), (h), (i), and (k) of this section.

(2) Except in a State that has an approved Medicaid Management Information System (MMIS) under Subpart C of Part 433 of this Chapter, a State plan must also provide for operating a Medicaid Quality Control (MQC) claims processing assessment system that meets the requirements of paragraphs (e), (g), (h), (j) and (k) of this section.

(d) *Basic elements of an MQC eligibility system.* The agency—

(1) Must operate the MQC system in accordance with the policies, sampling methodology, review procedures, and reporting forms and requirements specified in Medicaid quality control manuals issued by HCFA;

(2) Must select statistical samples of both active and negative case actions;

(3) Must review each case in the sample to identify eligibility errors; and

(4) Must review any claims pertaining to each active case to identify erroneous payments resulting from—

(i) Ineligibility; and

(ii) Recipient understated or overstated liability.

(5) In order to verify eligibility information, must conduct field investigations, including—

(i) Personal interviews for each case in the active case sample; and

(ii) Personal interviews for cases in the negative case action sample, to the extent necessary to verify erroneous eligibility determinations;

(6) Must use 6-month sampling periods, from April through September and from October through March; and

(7) May, at its option, increase its sample size above the minimum MQC requirements and claim FFP for the increased costs the agency incurs by exercising this option.

(e) *Basic elements of an MQC claims processing assessment system* (*CPAS*). The agency must—

(1) Operate the system in accordance with the policies, sampling methodology, review procedures, and reporting forms and requirements specified for CPAS in the *State Medicaid Manual* and instructions issued by HCFA;

(2) Identify deficiencies in the claims processing operations;

(3) Measure cost of deficiencies;

(4) Provide data to determine appropriate corrective action;

(5) Provide an assessment of the State's claims processing or that of its fiscal agent;

(6) Provide for a claim-by-claim review where justifiable by data; and

(7) Produce an audit trail that can be reviewed by HCFA or an outside auditor.

(f) *Reporting requirements for eligibility systems.* The agency must submit reports to HCFA, in the form and at the time specified by HCFA, including—

(1) A description of the State's sampling plan for active cases and negative cases;

(2) A monthly report on eligibility case reviews completed during the month for all cases in the active case sample for that month and selected cases from the negative case sample for that month;

(3) A monthly report on payment reviews completed during the month for cases in the active case sample. (States must wait 5 months after each sample month before accumulating claims paid for each case—through the fourth month following the sample month);

(4) A summary report on eligibility findings and payment error findings for all cases in the 6-month sample, to be submitted by May 31 of each year for the previous April-September sampling period, and by November 30 for the October-March sampling period; and

(5) Other data and reports that HCFA requests.

(g) *Reporting requirements for claims processing assessment systems.* The agency must submit reports and data to HCFA, in the form and at the time specified by HCFA. Except when HCFA authorizes less stringent reporting, States must submit:

(1) A monthly report on claims processing reviews sampled and on claims processing reviews completed during the month;

(2) A summary report on findings for all reviews in the 6-month sample to be submitted by the end of the 3rd month following the scheduled completion of reviews for that 6 month period; and

(3) Other data and reports as required by HCFA.

(h) *Access to records.* The agency, upon request, must provide HHS staff with access to all records pertaining to its MQC reviews to which the State has access, including information available under Part 435, Subpart J, of this chapter.

(i) *Corrective action.* The agency must—

(1) Take action to correct any eligibility, or negative case action errors found in the sample cases;

(2) Take administrative action to prevent or reduce the incidence of those errors; and

(3) By August 31 each year, submit to HCFA a report on its error rate analysis and a corrective action plan based on that analysis.

(j) *Corrective action as the result of MQC claims processing assessment system.* The agency must—

(1) Take action to correct those errors identified through the CPAS review and, if cost effective, to recover those funds erroneously spent;

(2) Take administrative action to prevent and reduce the incidence of those errors; and

(3) By August 31 of each year, submit to HCFA a report of its error analysis and a corrective action plan on the reviews conducted since the cut-off-date of the previous corrective action plan.

(k) *Protection of recipient rights.* Any individual performing activities under the Medicaid quality control program must do so in a manner consistent with §§ 435.902 and 436.901 of this subchapter concerning the rights of the recipient.

[43 FR 45188, Sept. 29, 1978, as amended at 48 FR 29453, June 24, 1983; 50 FR 21851, May 29, 1985; 51 FR 7210, Feb. 28, 1986; 52 FR 47933, Dec. 17, 1987]

§ 431.801 Disallowance of Federal financial participation for erroneous State payments (effective through September 1980).

(a) *Purpose and applicability*—(1) *Purpose.* This section establishes rules and procedures for disallowing Federal financial participation (FFP) in erroneous Medicaid payments due to eligibility errors, as detected through the Medicaid Quality Control (MQC) system required under § 431.800 of this subpart.

(2) *Applicability.* This section applies to States through the end of the April-September 1980 MQC review period. After September 30, 1980, HCFA will apply the performance standards specified in § 431.802.

(b) *Definitions.* For purposes of this section—"Base period" means a six month MQC sampling period used to calculate each State's error rate and the national standard. The initial base period is July through December 1978. For subsequent years, the base period is April through September.

"Eligibility errors" has the same meaning as specified in § 431.800(b).

"National standard" means the weighted mean of all State error rates for a base period.

"State error rate" means the rate of eligibility payment errors detected under the MQC system for each review period.

"State target error rate" means the error rate that a State must achieve in order to avoid a disallowance of FFP under this section. A State's target error rate is equal to the higher of the national standard or percent of that State's error rate during the base period.

(c) *Setting the State's error rate.* An error rate for each State will be determined for each MQC review period, in accordance with instructions issued by HCFA. Erroneous eligibility determinations by the Social Security Administration (SSA) of Supplemental Security Income (SSI) eligibility will not be included in determining the State's error rate. (If a State fails to complete a valid MQC review as required for any review period, HCFA will assign the State an error rate based on either the weighted average of its error rate in the last three review periods, a special Federal sample or audit, or Federal subsample.)

(d) *Establishing the target error rate.* Each year, after the end of the base period, HCFA will calculate a national standard and will notify each State agency what that State's target error rate is for the following April through September and October through March MQC review periods.

Example. The State's payment error rate in the base period is 20 percent. The national standard is 8 percent. To find the target error rate, we start with 20 percent and multiply by 84.3 percent which gives a target error rate of 16.9 percent. If this State reduces its error rate only to 18.2 percent during one of the subsequent disallowance periods, its FFP for that period may be reduced by 1.3 percent, the short fall from the 16.9 percent target.

(e) *Period for disallowance of FFP.* The State target error rate established for each base period will be used to determine whether the State is subject to a disallowance during the following April through September and October through March MQC review periods. During each of these two periods, a State will be subject to a reduction in FFP for program services (see § 433.10 of this subchapter) equal to the percentage points by which it exceeded its target error rate. The first disallowance period will be April through September, 1979.

(f) *Procedures for disallowance of FFP.* (1) HCFA will notify each State that is subject to a disallowance under paragraph (e) of this section. A State will have 65 days from the date on this notification in which to show that this disallowance should not be made because the State's failure to meet its target error rate was due to factors beyond its control.

(2) Events that will be considered by the Secretary in determining whether a State's failure to meet its target error rate was due to factors beyond its control include—

(i) Disasters such as fire, flood or civil disorders, that—

(A) Require the diversion of significant personnel normally assigned to Medicaid eligibility administration, or

(B) Destroyed or delayed access to significant records needed to make or maintain accurate eligibility determinations;

(ii) Strikes of State staff or other government or private personnel necessary to the determination of eligibility or processing of case changes;

(iii) Sudden and unanticipated workload changes which result from changes in Federal law and regulation, or rapid, unpredictable caseload growth in excess of, for example, 15 percent for a 6 month period; and

(iv) State actions resulting from incorrect written policy interpretation to the State by a Federal official resonably assumed to be in a position to provide such interpretation.

(3) The failure of a State to act upon necessary legislative changes or to obtain budget authorization for needed resources does not constitute a factor beyond the State's control.

(4) The Secretary may disallow the full amount calculated under paragraph (e) of this section or reduce the disallowance in whole or in part, to the extent he determines that the State's failure to meet its target error rate was due to factors beyond its control.

(5) A State may request reconsideration of a disallowance under this section in accordance with the procedures specified in § 430.42 of this chapter and 45 CFR Part 16.

[44 FR 12591, Mar. 7, 1979, as amended at 45 FR 6331, Jan. 25, 1980]

§ 431.802 Disallowance of Federal financial participation for erroneous State payments (effective October 1, 1980 through September 30, 1982).

(a) *Purpose and applicability*—(1) *Purpose.* This section establishes rules and procedures for disallowing Federal financial participation (FFP) in erroneous Medicaid payments due to eligibility errors, as detected through the Medicaid Quality Control (MQC) system required under § 431.800 of this subpart.

(2) *Applicability.* This section applies to all States for the 12-month annual assessment periods of October 1980-September 1981 and October 1981-September 1982. Beginning April 1, 1983, all States except Puerto Rico, Guam, the Virgin Islands, the Northern Mariana Islands, and American Samoa must follow the rules and procedures specified in § 431.803.

(b) *Definitions.* For purposes of this section—

"*Annual assessment period*" means the 12 month period, October 1 through September 30 and includes two 6-month review periods (October-March and April-September).

"*Base period*" means the 6 month MQC sample period from July through December 1978, used to calculate each State's error rate.

"*Eligibility errors*" has the same meaning as specified in § 431.800(b).

"*National standard*" means a 4 percent payment error rate.

"*State payment error rate*" means the rate of eligibility payment errors detected under the MQC system for an annual assessment period or a review period.

"*State target error rate*" means the error rate that a State must achieve in order to avoid a disallowance of FFP under this section.

(c) *Setting the State's payment error rate*—(1) A payment error rate for each State will be determined for each annual assessment period in accordance with instructions issued by HCFA.

(2) The State's payment error rate will not include erroneous eligibility determinations made by the Social Security Administration (SSA) of Supplementary Security Income (SSI) eligibility.

(3) If a State fails to complete a valid MQC review as required for any review period, HCFA will assign the State a payment error rate based on either—

(i) The weighted average of its payment error rate for the last three review periods;

(ii) A special Federal sample or audit; or

(iii) The Federal subsample.

(d) *Establishing the target error rate.* (1) Each State with a base period payment error rate in excess of 4 percent must reduce its payment error rate to 4 percent by the October 1982-September 1983 annual assessment period.

(2) This reduction must be made in three equal increments for each October-September annual assessment period beginning with the October 1980-September 1981 period.

(3) HCFA will establish each State's target error rate for the October 1980-September 1981 annual assessment period as follows:

(i) Multiply one-third times the amount by which the State's base period error rate exceeds 4 percent; and

(ii) Subtact this product from the State's base period error rate.

(4) HCFA will establish each State's target error rate for the October 1981-

September 1982 annual assessment period as follows:

(i) Multiply two-thirds times the amount by which the State's base period error rate exceeds 4 percent; and

(ii) Subtract this product from the State's base period error rate.

Example: Assume HCFA is establishing target error rates for the October 1981–September 1982 annual assessment period, and that the State in question has a base period error rate of 16 percent. HCFA will use the following formula to compute the State's target error rate:

(A) Four percent (the national standard) subtracted from sixteen percent (the State's base period error rate) equals 12 percent;

(B) Twelve percent multiplied by two-thirds equals 8 percent; and

(C) Eight percent subtracted from 16 percent equals an 8 percent target error rate.

(5) The State must meet the 4 percent national standard for all annual assessment periods after September 30, 1982.

(6) States with error rates in the base period at or below the 4 percent national standard must maintain that standard as their target error rate; but the rate may increase without penalty as long as it does not exceed the 4 percent national standard.

(7) Beginning with the October 1980–September 1981 annual assessment period and for all subsequent annual assessment periods, HCFA will notify each State agency of its progress in achieving the target error rates.

(e) *Computation for disallowance of FFP.* (1) If a State fails to meet its target error rate, HCFA will disallow FFP, as provided in this section, for each annual assessment period as appropriate (see paragraph (f) of this section for good faith examples).

(2) If a State fails to meet its target error rate, HCFA will compute the dollar amount to be disallowed.

(3) The dollar amount to be disallowed will be calculated as the weighted rate using error data from the AFDC and Medical Assistance Only or Medical Assistance and Others strata. The Medical Assistance Only stratum includes medical assistance cases for recipients who do not receive AFDC or SSI payments. The Medical Assistance and Others stratum includes Medical Assistance Only cases and SSI cases for States where Medicaid eligibility was not determined by SSA.

(4) The dollar amount to be disallowed will only include Federal matching funds for expenditures made for the AFDC and Medical Assistance Only or Medical Assistance and Others universes.

(5) HCFA will compute the dollar amount to be disallowed as follows:

(i) Subtract the target error rate from the computed weighted error payment rate;

(ii) If the difference is greater than zero, it will be multiplied by the Federal matching funds for the AFDC and Medical Assistance Only or Medical Assistance and Others universes. This product will be the amount of the disallowance.

(6) A State payment error rate for an annual assessment period will be the sum of the weighted payment error rates in the two 6-month review periods.

(7) The weights will be established as the percent of total annual payments that occur in each of the six month periods.

Example: The State's target error rate was 8 percent. During the first 6-month review period the payment error rate was 10 percent and the total payments made during that 6-month period were $20 million. During the second 6-month review period, the payment error rate was 9 percent and total payments were $30 million. The total payments in the annual assessment period were $50 million.

(i) The weight applied to the payment error rate for the first 6-month period would be .4 ($20 million divided by $50 million).

(ii) The weight applied to the payment error rate for the second 6-month period would be .6 ($30 million divided by $50 million).

(iii) Therefore, the payment error rate for the annual assessment period would be 9.4 percent or 4 percent (.4 x 10 percent for the first 6-month period) plus 5.4 percent (.6 x 9 percent for the second 6-month period).

(iv) Since the target error rate was 8 percent and the payment error rate was 9.4 percent, HCFA would disallow 1.4 percent of the amount of FFP claimed by the State for its Medicaid program for the annual assessment period.

(f) *Notice to States and showing of good faith*—(1) HCFA will notify a State that it will disallow matching funds because the State does not meet its target error rate.

(i) The State will have 65 days from the date on this notification to show that this disallowance should not be made because it made a good faith effort to meet the target error rate.

(ii) If the Secretary finds that the State did not meet its target error rate despite a good faith effort, HCFA will reduce the disallowance in whole, or in part, as the Secretary finds appropriate under the circumstances shown by the State.

(iii) A finding that a State did not meet the target error rate despite a good faith effort will be limited to extraordinary circumstances.

(2) Some examples of circumstances under which the Secretary may find that a State did not meet the target error rate despite a good faith effort are—

(i) Disasters such as a fire, flood, or civil disorders that—

(A) Require the diversion of significant personnel normally assigned to Medicaid eligibility administration, or

(B) Destroyed or delayed access to significant records needed to make or maintain accurate eligibility determinations;

(ii) Strikes of State staff or other government or private personnel necessary to the determination of eligibility or processing of case changes;

(iii) Sudden and unanticipated workload changes which result from changes in Federal law and regulation, or rapid, unpredictable caseload growth in excess of, for example, 15 percent for a 6 month period;

(iv) State actions resulting from incorrect written policy interpretation to the State by a Federal official reasonably assumed to be in a position to provide such interpretation; and

(v) The State timely developed and implemented a corrective action plan reasonably designed to meet the target error rate, but the target error rate was not achieved. In evaluating whether the State made a good faith effort in these circumstances, the Secretary will consider the following factors—

(A) Demonstrated commitment by top management to the error reduction program, e.g., priorities and goals clearly enunciated to staff, accountability for performance, availability of resources;

(B) Sufficiency and quality of systems designed to reduce errors that are operational in the State, e.g., BENDEX, SDX, monthly reporting, error prone profiles, local agency monitoring systems, computer clearances;

(C) Use of effective system and procedures for the statistical and program analysis of QC and related data, e.g., statistical tests, tabulations and cross-tabulations, error prone profiles, corrective action committees, special studies; and

(D) Effective management and execution of the corrective action process, e.g., assignment of responsibilities, milestones for completing tasks, substantial completion of tasks, monitoring of progress.

(3) The failure of a State to act upon necessary legislative changes or to obtain budget authorization for needed resources is not a ground for a waiver.

(4) A State may request reconsideration of a disallowance under this section in accordance with the procedures specified in 45 CFR Part 16.

[45 FR 6331, Jan. 25, 1980, as amended at 48 FR 29454, June 24, 1983; 48 FR 54232, Dec. 1, 1983]

§ 431.803 Disallowance of Federal financial participation for erroneous State payments (effective April 1 through December 31, 1983).

(a) *Purpose and applicability*—(1) *Purpose.* This section establishes rules and procedures for disallowing Federal financial participation (FFP) in erroneous medical assistance payments due to eligibility and beneficiary liability errors, as detected through the Medicaid quality control (MQC) system required under § 431.800.

(2) *Applicability.* This section applies to all States except Puerto Rico, Guam, the Virgin Islands, the Northern Mariana Islands, and American Samoa for the period of April 1

through December 31, 1983. Beginning January 1, 1984, those States must follow the rules and procedures specified in § 431.804.

(b) *Definitions.* For purposes of this section—

"*Administrator*" means the Administrator, Health Care Financing Administration or his or her designee.

"*Annual assessment period*" means the 12-month period October 1 through September 30 and includes two 6-month sample periods (October-March and April-September).

"*Beneficiary liability*" means—

(1) The amount of excess income that must be offset with incurred medical expenses to gain eligibility; or

(2) The amount of payment a recipient must make toward the cost of long term care.

"*Erroneous payments*" means the Medicaid payment that was made for an individual or family under review who—

(1) Was ineligible for the review month or, if full month coverage is not provided, at the time services were received; or

(2) Had not properly met beneficiary liability prior to receiving Medicaid services.

"*National standard*" means a 3-percent eligibility payment error rate.

"*State payment error rate*" means the ratio of erroneous payments for medical assistance to total expenditures for medical assistance (less payments to Supplemental Security Income beneficiaries in section 1634 contract States) for cases under review under the MQC system for each assessment period.

"*Technical error*" means errors in eligibility conditions that, if corrected, would not result in a difference in the amount of medical assistance paid. These errors include, but are not limited to, Work Incentive Program requirements, assignment of social security numbers, the requirement for a separate Medicaid application, monthly reporting requirements, and assignment of rights to third-party benefits as a condition of eligibility for Medicaid. Errors other than those listed must be approved by HCFA before they are classified as technical errors.

(c) *Setting the State's payment error rate.* (1) Each State must, for the April–September 1983 period and for each annual assessment period thereafter, have a payment error rate no greater than 3 percent or be subject to a disallowance in FFP.

(2) A payment error rate for each State is determined by HCFA for the period April-September 1983 and for each annual assessment period thereafter by computing the ratio of erroneous payments for medical assistance made on behalf of individuals or cases in the sample for services received during the review month to total expenditures for medical assistance made on behalf of individuals or cases in the sample for services received during the review month under the State plan in effect at the time of review. This ratio incorporates the findings of a federally re-reviewed subsample of the State's review findings and is projected to the universe of total medical assistance payments for a particular quarter in order to calculate the amount of disallowance, if any, under paragraph (d)(7) of this section.

(3) The State's payment error rate does not include payments made on behalf of individuals whose eligibility determinations were made exclusively by the Social Security Administration under an agreement under section 1634 of the Act.

(4) The amount of erroneous payments is determined as follows:

(i) For ineligible cases resulting from excess resources, the amount of error is the lesser of—

(A) The amount of the payments made on behalf of the family or individual for the review month; or

(B) The difference between the actual amount of countable resources of the family or individual for the review month and the State's applicable resource standard in the approved State plan.

(ii) For ineligible cases resulting from other than excess resources, the amount of error is the total amount of medical assistance payments made for the individual or family under review for the review month.

(iii) For erroneous payments resulting from failure to properly meet beneficiary liability, the amount of error is the lesser of—

(A) The amount of payments made on behalf of the family or individual for the review month; or

(B) The difference between the correct amount of beneficiary liability and the amount of beneficiary liability met by the individual or family for the review month.

(5) In determining the amount of erroneous payments, errors caused by technical errors are not included.

(6) If a State fails to cooperate in completing a valid MQC sample or individual reviews in a timely and appropriate fashion as required, HCFA will establish the State's payment error rate based on either—

(i) A special sample or audit;

(ii) The Federal subsample; or

(iii) Other arrangements as the Administrator may prescribe.

(7) When it is necessary for HCFA to exercise the authority in paragraph (c)(6) of this section, the amount that would otherwise be payable to the State under title XIX of the Act is reduced by the full costs incurred by HCFA in making these determinations. HCFA may make these determinations either directly or under contractual or other arrangements.

(d) *Computation of anticipated error rate.* (1) Before the beginning of each quarter, HCFA will project the anticipated State payment error rate for each State for that quarter. The anticipated error rate is based on the lower of the weighted average of the actual error rates for the two most recent 6-month review periods or the actual error rate of the most recently completed 6-month review period. In either case, the review period must have been completed by both the State and HCFA. Adjustments for the amount of erroneous payments due to excess resources and for technical errors will be made for all cases in the State and Federal samples for periods prior to October 1, 1983. Beginning with the October 1983–March 1984 sample period, these adjustments will be made only through the Federal difference resolution process if they are not reflected in the original State findings. If a State fails to provide HCFA with information needed to project an anticipated payment error rate, HCFA will assign the State an error rate as prescribed in paragraph (c)(6) of this section.

(2) The anticipated payment error rate established in paragraph (d)(1) of this section will then be adjusted by HCFA up to 25 percent based on the effect anticipated by HCFA of corrective action implemented by the State and a final anticipated payment error rate will be established by the Administrator. The following criteria will be used in assessing the effect of corrective action on the anticipated payment error rate:

(i) The State's correct identification of the major causes of errors.

(ii) The State's development of corrective actions designed to address the error causes identified by the State.

(iii) The State's implementation of the planned corrective actions.

(iv) The State's evaluation of whether or not corrective actions reduced the State's error rate.

(3) Based on the anticipated error rate established in paragraphs (d)(1) and (d)(2) of this section, HCFA will reduce the State's estimate of its FFP requirements for FFP for medical assistance for the quarter by the percentage by which the anticipated payment error rate exceeds the 3-percent national standard. This reduction will be applied against the State's total estimate of FFP for medical assistance expenditures (less payments to Supplemental Security Income beneficiaries in section 1634 contract States) prior to any other required reductions. The reduction will be noted on the State's grant award for the quarter and does not constitute a disallowance. The reduction, therefore, is not appealable.

(4) After the end of each quarter, an adjustment to the reduction will be made based on the State's actual expenditures.

(5) After the actual payment error rate has been established for an assessment period, HCFA will compute the actual amount of the disallowance and adjust the FFP payable to each State based on the difference between the amounts previously withheld for each of the quarters during the appropriate assessment period and the

amount that should have been withheld based on the State's actual final error rate. Within 30 days after the actual error rate is calculated for a particular quarter, HCFA will increase the State's grant award to the extent that the final disallowance amount is less than the amount previously withheld for that quarter.

(6) HCFA will compute the amount to be withheld or disallowed as follows:

(i) Subtract the 3-percent national standard from the State's anticipated or actual payment error rate percentage.

(ii) If the difference is greater than zero, the Federal medical assistance funds for the period, excluding payments for those individuals whose eligibility for Medicaid was determined exclusively or in part by the Social Security Administration under a section 1634 agreement, are multiplied by that percentage. This product is the amount of the disallowance or reduction.

(7) A State's payment error rate for an annual assessment period is the sum of the weighted average of the payment error rates in the two 6-month review periods.

(8) The weights are established as the percent of the total annual payments that occur in each of the 6-month periods.

Example: Assume that the State has an anticipated payment error rate of 6 percent for the April-June 1983 quarter. The State submits an estimate for medical assistance expenditures of $100,000 in FFP for that quarter. The State's actual expenditures for the April-June 1983 quarter justify only $90,000 in FFP. The actual payment error rate for that quarter is determined to be 8 percent.

(i) The State has a payment error rate in excess of the tolerance level equal to 3 percent (6 percent −3 percent).

(ii) The State's initial grant award for the April-June 1983 quarter is reduced by $3,000 ($100,000×0.03).

(iii) After the quarter ends, and the State's actual expenditures are known, HCFA determines that the actual reduction should have been $2,700 ($90,000×0.03).

(iv) When the grant award for the April-June 1983 quarter is finalized, an increasing adjustment of $300 ($3,000 −$2,700) is made.

(v) When the actual payment error rate for the April-June 1983 quarter is determined to be 8 percent, the State is 5 percent above the tolerance level. HCFA notifies the State of a final disallowance of $4,500 ($90,000×0.05). Since $2,700 has already been withheld from the State, HCFA would offset a future grant award by an additional $1,800 ($4,500 −$2,700).

(e) *Notice to States and showing of good faith.* (1) When the actual payment error rate data are finalized for the April-September 1983 assessment period and each annual assessment period thereafter, HCFA will establish each State's error rate and the amount of any disallowance. States that have error rates above the national standard will be notified by letter of their error rates and the amount of the potential disallowance.

(i) The State has 65 days from the date of receipt of this notification to show that this disallowance should not be made because it made a good faith effort to meet the national standard.

(ii) The Administrator finds that the State did not meet the national standard despite a good faith effort, HCFA will reduce the disallowance in whole, or in part, as the Administrator finds appropriate under the circumstances shown by the State.

(iii) A finding that a State did not meet the national standard despite a good faith effort will be limited to extraordinary circumstances.

(iv) The decision of the Administrator will be communicated to the State by letter.

(2) Some examples of circumstances under which the Administrator may find that a State did not meet the national standard despite a good faith effort are—

(i) Disasters such as fire, flood, or civil disorders that—

(A) Require the diversion of significant personnel normally assigned to Medicaid eligibility administration; or

(B) Destroyed or delayed access to significant records needed to make or maintain accurate eligibility determinations;

(ii) Strikes that result in the disruption of State staff or other government or private personnel necessary to the determination of eligibility or processing of case changes;

(iii) Sudden and unanticipated workload changes which result from changes in Federal law and regulation, or rapid, unpredictable caseload growth in excess of, for example, 15 percent for a 6-month period;

(iv) State actions resulting from incorrect written policy interpretations to the State by a Federal official reasonably assumed to be in a position to provide that interpretation; and

(v) The State timely developed and implemented a corrective action plan which the Administrator finds to be reasonably designed to meet the national standard, but the national standard was not achieved. In evaluating whether the State made a good faith effort in these circumstances, the Administrator will consider the following factors:

(A) Submittal of annual corrective action plans to the HCFA Regional Office by August 31 of each year with revisions to the plan made within 60 days of identification of additional error prone areas, other significant changes in the error rate, or changes in planned corrective action.

(B) The State must have operated an MQC eligibility program in accordance with the provisions of § 431.800.

(C) Demonstrated commitment by senior management to the error reduction program; for example, priorities and goals clearly enunciated to staff, accountability for performance, availability of resources.

(D) Sufficiency and quality of systems designed to reduce errors that are operational in the State; for example, BENDEX, SDX, monthly reporting, error prone profiles, local agency monitoring systems, computer clearances.

(E) Use of effective systems and procedures for the statistical and program analysis of QC and related data; for example, statistical tests, tabulations and cross tabulations, error prone profiles, corrective action committees, special studies.

(F) Effective management and execution of the corrective action process; for example, assignment of responsibilities, milestones for completing tasks, substantial completion of tasks, monitoring of progress.

(3) The failure of a State to act upon necessary legislative changes or to obtain budget authorization for needed resources is not a ground for a waiver.

(4) A State may request reconsideration of a disallowance under this section in accordance with the procedures specified in 45 CFR Part 16.

[48 FR 29454, June 24, 1983, as amended at 48 FR 54233, Dec. 1, 1983; 49 FR 4748, Feb. 8, 1984]

§ 431.804 Disallowance of Federal financial participation for erroneous State payments (effective January 1, 1984).

(a) *Purpose and applicability*—(1) *Purpose.* This section establishes rules and procedures for disallowing Federal financial participation (FFP) in erroneous medical assistance payments due to eligibility and beneficiary liability errors, as detected through the Medicaid quality control (MQC) system required under § 431.800.

(2) *Applicability.* This section will apply to all States except Puerto Rico, Guam, the Virgin Islands, the Northern Mariana Islands, and American Samoa beginning January 1, 1984.

(b) *Definitions.* For purposes of this section—"Administrator" means the Administrator, Health Care Financing Administration or his or her designee.

"Annual assessment period" means the 12-month period October 1 through September 30 and includes two 6-month sample periods (October-March and April-September).

"Beneficiary liability" means—

(1) The amount of excess income that must be offset with incurred medical expenses to gain eligibility; or

(2) The amount of payment a recipient must make toward the cost of long term care.

"Erroneous payments" means the Medicaid payment that was made for an individual or family under review who—

(1) Was ineligible for the review month or, if full month coverage is not provided, at the time services were received;

(2) Was ineligible to receive a service provided during the review month; or

(3) Had not properly met beneficiary liability prior to receiving Medicaid services.

"National standard" means a 3-percent eligibility payment error rate.

"State payment error rate" means the ratio of erroneous payments for medical assistance to total expenditures for medical assistance (less payments to Supplemental Security Income beneficiaries in section 1634 contract States) for cases under review under the MQC system for each assessment period.

"Technical error" means errors in eligibility conditions that, if corrected, would not result in a difference in the amount of medical assistance paid. These errors include, but are not limited to, Work Incentive Program requirements, assignment of social security numbers, the requirement for a separate Medicaid application, monthly reporting requirements, and assignment of rights to third-party benefits as a condition of eligibility for Medicaid. Errors other than those listed are subject to approval by HCFA before they are classified as technical errors.

(c) *Setting of State's payment error rate.* (1) Each State must, for each annual assessment period, have a payment error rate no greater than 3 percent or be subject to a disallowance in FFP.

(2) A payment error rate for each State is determined by HCFA for each annual assessment period by computing the ratio of erroneous payments for medical assistance made on behalf of individuals or cases in the sample for services received during the review month to total expenditures for medical assistance for that State made on behalf of individuals or cases in the sample for services received during the review month under its State plan in effect at the time of review. This ratio incorporates the findings of a federally re-reviewed subsample of the State's review findings and is projected to the universe of total medical assistance payments for calculating the amount of disallowance under paragraph (d)(7) of this section.

(3) The State's payment error rate does not include payments made on behalf of individuals whose eligibility determinations were made exclusively by the Social Security Administration under an agreement under section 1634 of the Act.

(4) The amount of erroneous payments is determined as follows:

(i) For ineligible cases resulting from excess resources, the amount of error is the lesser of—

(A) The amount of the payments made on behalf of the family or individual for the review month; or

(B) The difference between the actual amount of countable resources of the family or individual for the review month and the State's applicable resource standard in the approved State plan.

(ii) For ineligible cases resulting from other than excess resources, the amount or error is the total amount of medical assistance payments made for the individual or family under review for the review month.

(iii) For erroneous payments resulting from failure to properly meet beneficiary liability, the amount of error is the lesser of—

(A) The amount of payments made on behalf of the family or individual for the review month; or

(B) The difference between the correct amount of beneficiary liability and the amount of beneficiary liability met by the individual or family for the review month.

(iv) The amount of payments made for services provided during the review month for which the individual or family was not eligible.

(5) In determining the amount of erroneous payments, errors caused by technical errors are not included.

(6) If a State fails to cooperate in completing a valid MQC sample or individual reviews in a timely and appropriate fashion as required, which includes obtaining and using information available under Part 435, Subpart J, of this chapter, HCFA will establish the State's payment error rate based on either—

(i) A special sample or audit;

(ii) The Federal subsample; or

(iii) Other arrangements as the Administrator may prescribe.

(7) When it is necessary for HCFA to exercise the authority in paragraph

(c)(6) of this section, the amount that would otherwise be payable to the State under title XIX of the Act is reduced by the full costs incurred by HCFA in making these determinations. HCFA may make these determinations either directly or under contractual or other arrangements.

(d) *Computation of anticipated error rate.* (1) Before the beginning of each quarter, HCFA will project the anticipated medical assistance payment error rate for each State for that quarter. The anticipated error rate is the lower of the weighted average error rate of the two most recent 6-month review periods or the error rate of the most recent 6-month review period. In either case, cases in the review periods must have been completed by the State and HCFA. Adjustments for the amount of erroneous payments due to excess resources and for technical errors will be made for all cases in the State and Federal samples for periods prior to October 1, 1983. Beginning with the October 1983-March 1984 sample period, these adjustments will be made only through the Federal difference process if they are not reflected in the original State findings. If a State fails to provide HCFA with information needed to project anticipated excess erroneous expenditures, HCFA will assign the State on error rate as prescribed in paragraph (c)(6) of this section.

(2) If the State believes that the anticipated payment error rate established in paragraph (d)(1) of this section is significantly unrepresentative of current experience, the State may submit statistically valid evidence, conforming to criteria set forth in paragraph (d)(3) of this section, which demonstrates with more recent data that the State's latest error rate is significantly below the error rate projected in paragraph (d)(1) of this section. The State must complete the following steps in submitting its evidence:

(i) The State must inform HCFA of its intent to submit evidence at least 75 days prior to the beginning of the quarter. The evidence submitted by the State may take the form of data from—

(A) A special sample; or

(B) An MQC sample for a more recent period than was used to establish the anticipated payment error rate under the provisions of paragraph (d)(1) of this section.

(ii) If the evidence is from a special sample, it must be submitted to HCFA at least 40 days prior to the beginning of the quarter for which the projection is being made and may be used for projecting the error rate for two quarters. If the State elects to submit data from a more recent MQC sample, the evidence must be submitted by the due date prescribed by HCFA.

(iii) The statistical evidence supplied by the State is subject to validation by HCFA. If a State submits error rate findings from the regular MQC sample for a more recent period, the validation will consist of the Federal re-review and the error rate will be adjusted based on Federal findings. If the data submitted by the State are from a special sample, the validity of the sample data will be determined through acceptance sampling. The acceptance sampling procedure used by HCFA will be the Military Standard 105D, double sampling with an Acceptable Quality Level of 4 percent at Inspection Level II (Normal). A case finding will be considered defective if either the eligibility/liability or payment finding is considered incorrect in the validation. If the data submitted by the State are determined to be invalid, the anticipated error rate established in paragraph (d)(1) of this section will remain as the anticipated error rate.

(3) Evidence submitted by the State to establish that the anticipated payment error rate determined in paragraph (d)(1) of this section is statistically significantly different from current State experience must be shown to be statistically significantly different by use of the Student T Test (1-tail test at the 90-percent level) and must be shown to meet the following criteria:

(i) Evidence must consist of a completed review of all cases in a statistically valid random sample of the total Medicaid case load (excluding SSI cases in 1634 States). Samples may be selected in a random or stratified manner. (Examples of strata that may be used are error-prone and nonerror-prone, or high dollar and low dollar cases.) If the State plans to use more recent MQC data, the data must consist of one or more consecutive full month samples. All cases selected for a sample must be used and submitted to HCFA as evidence. Data from one or more partial or nonconsecutive month samples will not be accepted.

(ii) The cases must be selected from a period later than that used to establish the anticipated payment error rate under paragraph (d)(1) of this section.

(iii) The minimum sample size must be 100 completed cases.

(iv) An accurate and thorough review of all cases in the sample sufficient to identify and verify eligibility and payment errors must be completed or the reason for not completing all cases must be documented.

(v) Erroneous payments must be defined in the same way as they are defined in paragraph (b) of this section.

(vi) A payment error rate must be computed in a manner that is equivalent to that specified in paragraph (c) of this section.

(4) Based on the anticipated error rate established in paragraph (d)(1) or (d)(2) of this section, HCFA will reduce the State's estimate of its requirements for FFP for medical assistance for the quarter by the percentage by which the anticipated payment error rate exceeds the 3-percent national standard. This reduction will be applied against the State's total estimate of FFP for medical assistance expenditures (less payments to Supplemental Security Income beneficiaries in 1634 contract States) prior to any other required reductions. The reduction will be noted on the State's grant award for the quarter and does not constitute a disallowance, and, therefore, is not appealable.

(5) After the end of each quarter, an adjustment to the reduction will be made based on the State's actual expenditures.

(6) After the actual payment error rate has been established for each annual assessment period. HCFA will compute the actual amount of the disallowance and adjust the FFP payable to each State based on the difference between the amounts previously withheld for each of the quarters during the appropriate assessment period and the amount that should have been withheld based on the State's actual final error rate. If HCFA determines that the amount withheld for the period exceeds the amount of the actual disallowance, the excess amount withheld will be returned to the States through the normal grant awards process within 30 days of the date the actual disallowance is calculated.

(7) HCFA will compute the amount to be withheld or disallowed as follows:

(i) Subtract the 3-percent national standard from the State's anticipated or actual payment error rate percentage.

(ii) If the difference is greater than zero, the Federal medical assistance funds for the period, excluding payments for those individuals whose eligibility for Medicaid was determined exclusively by the Social Security Administration under a section 1634 agreement, are multiplied by that percentage. This product is the amount of the disallowance or withholding.

(8) A State's payment error rate for an annual assessment period is the sum of the weighted average of the payment error rates in the two 6-month review periods comprising the annual assessment period.

(9) The weights are established as the percent of the total annual payments that occur in each of the 6-month periods.

(See § 431.803(d)(9) for an example of a disallowance computation)

(e) *Notice of States and showing of good faith.* (1) When the actual payment error rate data are finalized for each annual assessment period beginning October 1, 1983, HCFA will establish each State's error rate and the amount of any potential disallowance. States that have error rates above the national standard will be notified by letter of their error rates and the amount of the potential disallowance.

(i) The State has 65 days from the date of receipt of this notification to show that this disallowance should not be made because it made a good faith effort to meet the national standard.

(ii) If the Administrator finds that the State did not meet the national standard despite a good faith effort, HCFA will reduce the disallowance in whole, or in part, as the Administrator finds appropriate under the circumstances shown by the State.

(iii) A finding that a State did not meet the national standard despite a good faith effort will be limited to extraordinary circumstances.

(iv) The decision of the Administrator will be communicated to the State by letter.

(2) Some examples of circumstances under which the Administrator may find that a State did not meet the national standard despite a good faith effort are—

(i) Disasters such as fire, flood, or civil disorders that—

(A) Require the diversion of significant personnel normally assigned to Medicaid eligibility administration; or

(B) Destroyed or delayed access to significant records needed to make or maintain accurate eligibility determinations;

(ii) Strikes that result in the disruption of State staff or other government or private personnel necessary to the determination of eligibility or processing of case changes.

(iii) Sudden and unanticipated workload changes which result from changes in Federal law and regulation, or rapid, unpredictable caseload growth in excess of, for example, 15 percent for a 6-month period;

(iv) State actions resulting from incorrect written policy interpretations to the State by a Federal official reasonably assumed to be in a position to provide that interpretation; and

(v) The State timely developed and implemented a corrective action plan which the Administrator finds to be reasonably designed to meet the target error rate, but the national standard was not achieved. In evaluating whether the State made a good faith effort in these circumstances, the Administrator will consider the following factors:

(A) Submittal of annual corrective action plans to the HCFA Regional Office by August 31 of each year with revisions to the plan made within 60 days of identification of additional error prone areas, other significant changes in the error rate, or changes in planned corrective action.

(B) The State must have operated an MQC eligibility program in accordance with the provisions of § 431.800.

(C) Demonstrated commitment by senior management to the error reduction program; for example, priorities and goals clearly enunciated to staff, accountability for performance, availability of resources.

(D) Sufficiency and quality of systems designed to reduce errors that are operational in the State; for example, BENDEX, SDX, monthly reporting, error prone profiles, local agency monitoring systems, computer clearances.

(E) Use of effective systems and procedures for the statistical and program analysis of QC and related data; for example, statistical tests, tabulations and cross tabulations, error prone profiles, corrective action committees, special studies.

(F) Effective management and execution of the corrective action process; for example, assignment of responsibilities, milestones for completing tasks, substantial completion of tasks, monitoring of progress.

(3) The failure of a State to act upon necessary legislative changes or to obtain budget authorization for needed resources is not a ground for a waiver.

(4) A State may request reconsideration of a disallowance under this section in accordance with the procedures specified in 45 CFR Part 16.

[48 FR 54233, Dec. 1, 1983, as amended at 49 FR 4750, Feb. 8, 1984; 51 FR 7210, Feb. 28, 1986]

PART 432—STATE PERSONNEL ADMINISTRATION

Subpart A—General Provisions

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AUTHORITY: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

SOURCE: 43 FR 45199, Sept. 29, 1978, unless otherwise noted.

Subpart A—General Provisions

§ 432.1 Basis and purpose.

This part prescribes regulations to implement section 1902(a)(4) of the Act, which relates to a merit system of State personnel administration and training and use of subprofessional staff and volunteers in State Medicaid programs, and section 1903(a), rates of FFP for Medicaid staffing and training costs. It also prescribes regulations, based on the general administrative authority in section 1902(a)(4), for State training programs for all staff.

§ 432.2 Definitions.

As used in this part—

Community service aides means subprofessional staff, employed in a variety of positions, whose duties are an integral part of the agency's responsibility for planning, administration, and for delivery of health services.

Directly supporting staff means secretarial, stenographic, and copying personnel and file and records clerks who provide clerical services that directly support the responsibilities of skilled professional medical personnel, who are directly supervised by the skilled professional medical personnel, and who are in an employer-employee relationship with the Medicaid agency.

Fringe benefits means the employer's share of premiums for workmen's compensation, employees' retirement, unemployment compensation, health insurance, and similar expenses.

Full-time training means training that requires employees to be relieved of all responsibility for performance of current agency work to participate in a training program.

Part-time training means training that allows employees to continue full-time in their agency jobs or requires only partial reduction of work activities to participate in the training activity.

Skilled professional medical personnel means physicians, dentists, nurses, and other specialized personnel who have professional education and training in the field of medical care or appropriate medical practice and who are in an employer-employee relationship with the Medicaid agency. It does not include other nonmedical health professionals such as public administrators, medical analysts, lobbyists, senior managers or administrators of public assistance programs or the Medicaid program.

Staff of other public agencies means skilled professional medical personnel and directly supporting staff who are employed in State or local agencies other than the Medicaid agency who perform duties that directly relate to the administration of the Medicaid program.

Subprofessional staff means persons performing tasks that demand little or no formal education; a high school diploma; or less than 4 years of college.

Supporting staff means secretarial, stenographic, clerical, and other subprofessional staff whose activities are directly necessary to the carrying out of the functions which are the responsibility of skilled professional medical personnel, as defined in this section.

Training program means a program of educational activities based on the agency's training needs and aimed at insuring that agency staff acquire the knowledge and skills necessary to perform their jobs.

Volunteer means a person who contributes personal service to the community through the agency's program but is not a replacement or substitute for paid staff.

[43 FR 45199, Sept. 29, 1978, as amended at 50 FR 46663, Nov. 12, 1985, 50 FR 49389, Dec. 2, 1985]

§ 432.10 Standards of personnel administration.

(a) *State plan requirement.* A State plan must provide that the requirements of paragraphs (c) through (h) of this section are met.

(b) *Terms.* In this section, "standards" refer to those specified in paragraph (c) of this section.

(c) *Methods of personnel administration.* Methods of personnel administration must be established and maintained, in the Medicaid agency and in local agencies administering the program, in conformity with:

(1) [Reserved]

(2) 5 CFR Part 900, Subpart F, Administration of the Standards for Merit System of Personnel Administration.

(d) *Compliance of local jurisdictions.* The Medicaid agency must have in effect methods to assure compliance with the standards by local jurisdictions included in the plan.

(e) *Review and adequacy of State laws, regulations, and policies.* The agency must—

(1) Assure that the U.S. Civil Service Commission has determined the adequacy of current State laws, regulations, and policy statements that effect methods of personnel administration in conformity with the standards, and

(2) Submit any changes in them to the Commission for review.

(f) *Statements of acceptance by local agencies.* If the Medicaid agency changes from a State-administered to a State-supervised, locally administered program, it must obtain statements of acceptance of the standards from the local agencies.

(g) *Affirmative action plan.* The Medicaid agency must have in effect an affirmative action plan for equal employment opportunity, that includes specific action steps and timetables to assure that opportunity, and meets all other requirements of 45 CFR 70.4.[1]

(h) *Submittal of requested materials.* The Medicaid agency must submit to HHS, upon request, copies of the affirmative action plan and of the State and local materials that assure compliance with the standards.

[43 FR 45199, Sept. 29, 1978, as amended at 45 FR 24883, Apr. 11, 1980]

Subpart B—Training Programs; Subprofessional and Volunteer Programs

§ 432.30 Training programs: General requirements.

(a) A State plan must provide for a program of training for Medicaid agency personnel. (See also §§ 432.31 and 432.32 for training programs for subprofessional staff and for volunteers.)

(b) The program must—

(1) Include initial inservice training for newly appointed staff, and continuing training opportunities to improve the operation of the program;

(2) Be related to job duties performed or to be performed by the persons trained; and

(3) Be consistent with the program objectives of the agency.

§ 432.31 Training and use of subprofessional staff.

(a) *State plan requirement.* A State plan must provide for the training and effective use of subprofessional staff as community service aides, in accordance with the requirements of this section.

(b) *Recruitment and selection.* The Medicaid agency must have methods of recruitment and selection that afford opportunity for full-time or part-time employment of persons of low income, including:

(1) Young, middle-aged, and older persons;

(2) Physically and mentally disabled; and

(3) Recipients.

(c) *Merit system.* Subprofessional positions must be subject to merit system requirements except where special exemption is approved on the basis of a State alternative plan for employment of disadvantaged persons.

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[1] Editorial Note: The regulations formerly contained in 45 CFR 70.4 were revised and reissued by the Office of Personnel Management at 5 CFR Part 900, (Subpart F).

(d) *Staffing plan.* The agency staffing plan must include the kinds of jobs that subprofessional staff can perform.

(e) *Career service.* The agency must have a career service program that allows persons:

(1) To enter employment at the subprofessional level; and

(2) To progress to positions of increasing responsibility and reward:

(i) In accordance with their abilities; and

(ii) Through work experience and pre-service and in-service training.

(f) *Training, supervision and supportive services.* The agency must have an organized training program, supervision, and supportive services for subprofessional staff.

(g) *Progressive expansion.* The agency must provide for annual increase in the number of subprofessional staff until:

(1) An appropriate ratio of subprofessional and professional staff has been achieved; and

(2) There is maximum use of subprofessional staff as community aides in the operation of the program.

§ 432.32 Training and use of volunteers.

(a) *State plan requirement.* A State plan must provide for the training and use of non-paid or partially paid volunteers in accordance with the requirements of this section.

(b) *Functions of volunteers.* The Medicaid agency must make use of volunteers in:

(1) Providing services to applicants and recipients; and

(2) Assisting any advisory committees established by the agency.

As used in this paragraph, "partially paid volunteers" means volunteers who are reimbursed only for actual expenses incurred in giving service, without regard to the value of the service or the time required to provide it.

(c) *Staffing.* The agency must designate a position whose incumbent is responsible for:

(1) The development, organization, and administration of the volunteer program; and

(2) Coordination of the program with related functions.

(d) *Recruitment, selection, training, and supervision.* The agency must have:

(1) Methods of recruitment and selection that assure participation of volunteers of all income levels, in planning capacities and service provision; and

(2) A program of organized training and supervision of volunteers.

(e) *Reimbursement of expenses.* The agency must—

(1) Reimburse volunteers for actual expenses incurred in providing services; and

(2) Assure that no volunteer is deprived of the opportunity to serve because of the expenses involved.

(f) *Progressive expansion.* The agency must provide for annual increase in the number of volunteers used until the volunteer program is adequate for the achievement of the agency's service goals.

Subpart C—Staffing and Training Expenditures

§ 432.45 Applicability of provisions in subpart.

The rates of FFP specified in this Subpart C do not apply to State personnel who conduct survey activities and certify facilities for participation in Medicaid, as provided for under section 1902(a)(33)(B) of the Act.

[50 FR 46663, Nov. 12, 1985; 50 FR 49389, Dec. 2, 1985]

§ 432.50 FFP: Staffing and training costs.

(a) *Availability of FFP.* FFP is available in expenditures for salary or other compensation, fringe benefits, travel, per diem, and training, at rates determined on the basis of the individual's position, as specified in paragraph (b) of this section.

(b) *Rates of FFP.* (1) For skilled professional medical personnel and directly supporting staff of the Medicaid agency or of other public agencies (as defined in § 432.2), the rate is 75 percent.

(2) For personnel engaged directly in the operation of mechanized claims processing and information retrieval systems, the rate is 75 percent.

(3) For personnel engaged in the design, development, or installation of mechanized claims processing and information retrieval systems, the rate is 50 percent for training and 90 percent for all other costs specified in paragraph (a) of this section.

(4) [Reserved]

(5) For personnel administering family planning services and supplies, the rate is 90 percent.

(6) For all other staff of the Medicaid agency or other public agencies providing services to the Medicaid agency, and for training and other expenses of volunteers, the rate is 50 percent.

(c) *Application of rates.* (1) FFP is prorated for staff time that is split among functions reimbursed at different rates.

(2) Rates of FFP in excess of 50 percent apply only to those portions of the individual's working time that are spent carrying out duties in the specified areas for which the higher rate is authorized.

(3) The allocation of personnel and staff costs must be based on either the actual percentages of time spent carrying out duties in the specified areas, or another methodology approved by HCFA.

(d) *Other limitations for FFP rate for skilled professional medical personnel and directly supporting staff*—(1) *Medicaid agency personnel and staff.* The rate of 75 percent FFP is available for skilled professional medical personnel and directly supporting staff of the Medicaid agency if the following criteria, as applicable, are met:

(i) The expenditures are for activities that are directly related to the administration of the Medicaid program, and as such do not include expenditures for medical assistance;

(ii) The skilled professional medical personnel have professional education and training in the field of medical care or appropriate medical practice. "Professional education and training" means the completion of a 2-year or longer program leading to an academic degree or certificate in a medically related profession. This is demonstrated by possession of a medical license, certificate, or other document issued by a recognized National or State medical licensure or certifying organization or a degree in a medical field issued by a college or university certified by a professional medical organization. Experience in the administration, direction, or implementation of the Medicaid program is not considered the equivalent of professional training in a field of medical care.

(iii) The skilled professional medical personnel are in positions that have duties and responsibilities that require those professional medical knowledge and skills.

(iv) A State-documented employer-employee relationship exists between the Medicaid agency and the skilled professional medical personnel and directly supporting staff; and

(v) The directly supporting staff are secretarial, stenographic, and copying personnel and file and records clerks who provide clerical services that are directly necessary for the completion of the professional medical responsibilities and functions of the skilled professional medical staff. The skilled professional medical staff must directly supervise the supporting staff and the performance of the supporting staff's work.

(2) *Staff of other public agencies.* The rate of 75 percent FFP is available for staff of other public agencies if the requirements specified in paragraph (d)(1) of this section are met and the public agency has a written agreement with the Medicaid agency to verify that these requirements are met.

(e) *Limitations on FFP rates for staff in mechanized claims processing and information retrieval systems.* The special matching rates for persons working on mechanized claims processing and information retrieval systems (paragraphs (b)(2) and (3) of this section) are applicable only if the design, development and installation, or the operation, have been approved by the Administrator in accordance with Part 433, Subchapter C, of this chapter.

[43 FR 45199, Sept. 29, 1978, as amended at 46 FR 48566, Oct. 1, 1981; 50 FR 46663, Nov. 12, 1985]

§ 432.55 Reporting training and administrative costs.

(a) *Scope.* This section identifies activities and costs to be reported as training or administrative costs on quarterly estimate and expenditure reports to HCFA.

(b) *Activities and costs to be reported on training expenditures.* (1) For fulltime training (with no assigned agency duties): Salaries, fringe benefits, dependency allowances, travel, tuition, books, and educational supplies.

(2) For part-time training: Travel, per diem, tuition, books and educational supplies.

(3) For State and local Medicaid agency staff development personnel (including supporting staff) assigned fulltime training functions: Salaries, fringe benefits, travel, and per diem. Costs for staff spending less than full time on training for the Medicaid program must be allocated between training and administration in accordance with § 433.34 of this subchapter.

(4) For experts engaged to develop or conduct special programs: Salary, fringe benefits, travel, and per diem.

(5) For agency training activities directly related to the program: Use of space, postage, teaching supplies, and purchase or development of teaching materials and equipment, for example, books and audiovisual aids.

(6) For field instruction in Medicaid: Instructors' salaries and fringe benefits, rental of space, travel, clerical assistance, teaching materials and equipment such as books and audiovisual aids.

(c) *Activities and costs not to be reported as training expenditures.* The following activities are to be reported as administrative costs:

(1) Salaries of supervisors (day-to-day supervision of staff is not a training activity); and

(2) Cost of employing students on a temporary basis, for instance, during summer vacation.

[43 FR 45199, Sept. 29, 1978, as amended at 44 FR 17935, Mar. 23, 1979]

PART 433—STATE FISCAL ADMINISTRATION

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AUTHORITY: Secs. 1102, 1137, 1902(a)(4), 1902(a)(25), 1902(a)(45), 1903(a)(3), 1903(d)(2), 1903(d)(5), 1903(o), 1903(p), 1903(r), and 1912 of the Social Security Act; 42 U.S.C. 1302, 1320b-7, 1396a(a)(4), 1396a(a)(25), 1396a(a)(45), 1396b(a)(3), 1396b(d)(2), 1396b(d)(5), 1396b(o), 1396b(p), 1396b(r) and 1396k, unless otherwise noted.

SOURCE: 43 FR 45201, Sept. 29, 1978, unless otherwise noted.

§ 433.1 Purpose.

This part specifies the rates of FFP for services and administration, and prescribes requirements, prohibitions, and FFP conditions relating to State fiscal activities.

Subpart A—Federal Matching Provisions

§ 433.8 Implementation of progressive reductions in FFP for fiscal years 1982–1984.

Procedures for the implementation of progressive reductions in FFP for fiscal years 1982-1984, authorized under sections 1903 (s) and (t) of the Act, are described in Subpart E of this part.

[47 FR 43348, Sept. 30, 1982]

§ 433.10 Rates of FFP for program services.

(a) *Basis.* Sections 1903(a)(1), 1903(g), and 1905(b) provide for payments to States, on the basis of a Federal medical assistance percentage, for part of their expenditures for services under an approved State plan.

(b) *Federal medical assistance percentage (FMAP)—Computation.* The FMAP is determined by the formula described in section 1905(b) of the Act. Under the formula, if a State's per capita income is equal to the national average per capita income, the Federal share is 55 percent. If a State's per capita income exceeds the national average, the Federal share is lower, with a statutory minimum of 50 percent. If a State's per capita income is lower than the national average, the Federal share is increased, with a statutory maximum of 83 percent. The formula used in determining the State and Federal share is as follows:

State share=(State per capita income)^2 (National per capita income)^2 ×45 percent
Federal share=100 percent minus the State share (with a minimum of 50 percent and a maximum of 83 percent)

The formula provides for squaring both the State and national average per capita incomes; this procedure magnifies any difference between the State's income and the national average. Consequently, Federal matching to lower income States is increased, and Federal matching to higher income States is decreased, within the statutory 50–83 percent limits. The FMAP for Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa is set by statute at 50 percent and is subject to dollar limitations specified in section 1108 of the Act.

(c) *Special provisions.* (1) Under section 1903(a)(5) of the Act, the Federal share of State expenditures for family planning services is 90 percent.

(2) Under section 1905(b), the Federal share of State expenditures for services provided through Indian Health Service facilities is 100 percent.

(3) Under section 1903(g), the FMAP is reduced if the State does not have an effective program to control use of institutional services.

[43 FR 45201, Sept. 29, 1978, as amended at 46 FR 48559, Oct. 1, 1981; 51 FR 41350, Nov. 14, 1986]

§ 433.15 Rates of FFP for administration.

(a) *Basis.* Section 1903(a) (2) through (5) and (7) of the Act provide for payments to States, on the basis of specified percentages, for part of their expenditures for administration of an approved State plan.

(b) *Activities and rates.* (1) [Reserved]

(2) Administration of family planning services: 90 percent. (Section 1903(a)(5); 42 CFR 432.50(b)(5).)

(3) Design, development, or installation of mechanized claims processing and information retrieval systems: 90 percent. (Section 1903(a)(3)(A)(i); 42 CFR Part 433, Subpart C, and § 432.50(b)(3).)

(4) Operation of mechanized claims processing and information retrieval systems: 75 percent. (Section 1903(a)(3)(B); 42 CFR Part 433, Subpart C and § 432.50(b)(2).)

(5) Compensation and training of skilled professional medical personnel and staff directly supporting those personnel if the criteria specified in § 432.50 (c) and (d) are met: 75 percent. (Section 1903(a)(2); 42 CFR 432.50(b)(1).)

(6)(i) Funds expended for the performance of medical and utilization review by a PRO under a contract entered into under section 1902(d) of the Act: 75 percent (section 1903(a)(3)(C) of the Act).

(ii) If a State contracts for medical and utilization review with any individual or organization not designated under Part B of Title XI of the Act, funds expended for such review will be reimbursed as provided in paragraph (b)(7) of this section.

(7) All other activities the Secretary finds necessary for proper and efficient administration of the State plan: 50 percent. (Section 1903(a)(7).) (See also § 455.300 of this subchapter for FFP at 90 percent for State Medicaid fraud control units under section 1903(a)(6).)

[43 FR 45201, Sept. 29, 1978, as amended at 46 FR 48566, Oct. 1, 1981; 46 FR 54744, Nov. 4, 1981; 50 FR 15327, Apr. 17, 1985; 50 FR 46664, Nov. 12, 1985]

Subpart B—General Administrative Requirements

AUTHORITY: Secs. 1102, 1902(a)(4), 1902(a)(18), 1902(a)(25), 1903(a)(1), 1903(d)(2), 1903(d)(3), 1903(o), 1903(p), 1912 and 1917 of the Social Security Act (42 U.S.C. 1302, 1396a(a)(4), 1396a(a)(18), 1396a(a)(25), 1396b(a)(1), 1396b(d)(2), 1396b(d)(3), 1396b(o), 1396b(p), 1396k and 1396p), unless otherwise noted.

§ 433.32 Fiscal policies and accountability.

A State plan must provide that the Medicaid agency and, where applicable, local agencies administering the plan will—

(a) Maintain an accounting system and supporting fiscal records to assure that claims for Federal funds are in accord with applicable Federal requirements;

(b) Retain records for 3 years from date of submission of a final expenditure report;

(c) Retain records beyond the 3-year period if audit findings have not been resolved; and

(d) Retain records for nonexpendable property acquired under a Federal grant for 3 years from the date of final disposition of that property.

[44 FR 17935, Mar. 23, 1979]

§ 433.33 State financial participation.

A State plan must provide that—

(a) State (as distinguished from local) funds will be used both for medical assistance and administration;

(b) State funds will be used to pay at least 40 percent of the non-Federal share of total expenditures under the plan; and

(c) State and Federal funds will be apportioned among the political subdivisions of the State on a basis that assures that—

(1) Individuals in similar circumstances will be equitably treated throughout the State; and

(2) If there is local financial participation, lack of funds from local sources will not result in lowering the amount, duration, scope, or quality of services or level of administration under the plan in any part of the State.

[44 FR 17935, Mar. 23, 1979]

§ 433.34 Cost allocation.

A State plan under Title XIX of the Social Security Act must provide that the single or appropriate Agency will have an approved cost allocation plan on file with the Department in accordance with the requirements contained in Subpart E of 45 CFR Part 95. Subpart E also sets forth the effect on FFP if the requirements contained in that subpart are not met.

[47 FR 17490, Apr. 23, 1982]

§ 433.35 Equipment—Federal financial participation.

Claims for Federal financial participation in the cost of equipment under the Medicaid Program are determined in accordance with Subpart G of 45 CFR Part 95. Requirements concerning the management and disposition of equipment under the Medicaid Program are also prescribed in Subpart G of 45 CFR Part 95.

[47 FR 41564, Sept. 21, 1982]

§ 433.36 Liens and recoveries.

(a) *Basis and purpose.* This section implements sections 1902(a)(18) and 1917(a) and (b) of the Act, which describe the conditions under which an agency may impose a lien against a recipient's property, and when an agency may make an adjustment or recover funds in satisfaction of the claim against the individual's estate or real property.

(b) *Definition of property.* For purposes of this section, "property" includes the homestead and all other personal and real property in which the recipient has a legal interest.

(c) *State plan requirement.* If a State chooses to impose a lien against an individual's real property (or as provided in paragraph (g)(1) of this section, personal property), the State plan must provide that the provisions of paragraphs (d) through (i) of this section are met.

(d) *Procedures.* The State plan must specify the process by which the State will determine that an institutionalized individual cannot reasonably be expected to be discharged from the medical institution and return home as provided in paragraph (g)(2)(ii) of this section. The description of the process must include the type of notice to be given the individual, the process by which the individual will be given the opportunity for a hearing, the hearing procedures, and by whom and on what basis the determination that the individual cannot reasonably be expected to be discharged from the institution will be made. The notice to the individual must explain what is meant by the term lien, and that imposing a lien does not mean that the individual will lose ownership of the home.

(e) *Definitions.* The State plan must define the following terms used in this section:

(1) Individual's home.

(2) Equity interest in home.

(3) Residing in the home for at least 1 (or 2) year(s).

(4) On a continuing basis.

(5) Discharge from the medical institution and return home.

(6) Lawfully residing.

(f) *Exception.* The State plan must specify the criteria by which a son or daughter can establish to the agency's satisfaction that he or she has been providing care which permitted the individual to reside at home rather than in an institution, as provided in paragraph (h)(2)(iii)(B) of this section.

(g) *Lien provisions*—(1) *Incorrect payments.* The agency may place a lien against an individual's property, both personal and real, before his or her death because of Medicaid claims paid or to be paid on behalf of that individual following a court judgement which determined that benefits were incorrectly paid for that individual.

(2) *Correct payments.* Except as provided in paragraph (g)(3) of this section, the agency may place a lien against the real property of an individual at any age before his or her death because of Medicaid claims paid or to be paid for that individual when—

(i) An individual is an inpatient of a medical institution and must, as a condition of receiving services in the institution under the State plan, apply his or her income to the cost of care as provided in §§435.725, 435.832 and 436.832; and

(ii) The agency determines that he or she cannot reasonably be expected to be discharged and return home. The agency must notify the individual of its intention to make that determination and provide an opportunity for a hearing in accordance with State established procedures before the determination is made. The notice to an individual must include an explanation of liens and the effect on an individual's ownership of property.

(3) *Restrictions on placing liens.* The agency may not place a lien on an individual's home under paragraph (g)(2) of this section if any of the following individuals is lawfully residing in the home:

(i) The spouse;

(ii) The individual's child who is under age 21 or blind or disabled as defined in the State plan; or

(iii) The individual's sibling (who has an equity interest in the home, and who was residing in the individual's home for at least one year immediately before the date the individual was admitted to the medical institution).

(4) *Termination of lien.* Any lien imposed on an individual's real property under paragraph (g)(2) of this section will dissolve when that individual is discharged from the medical institution and returns home.

(h) *Adjustments and recoveries.* (1) The agency may make an adjustment or recover funds for Medicaid claims correctly paid for an individual as follows:

(i) From the estate of any individual who was 65 years of age or older when he or she received Medicaid; and

(ii) From the estate or upon sale of the property subject to a lien when the individual is institutionalized as described in paragraph (g)(2) of this section.

(2) The agency may make an adjustment or recovery under paragraph (h)(1) of this section only:

(i) After the death of the individual's surviving spouse; and

(ii) When the individual has no surviving child under age 21 or blind or disabled as defined in the State plan; and

(iii) In the case of liens placed on an individual's home under paragraph (g)(2) of this section, when there is no—

(A) Sibling of the individual residing in the home, who has resided there for at least one year immediately before the date of the individual's admission to the institution, and has resided there on a continuous basis since that time; or

(B) Son or daughter of the individual residing in the home, who has resided there for at least two years immediately before the date of the individual's admission to the institution, has resided there on a continuous basis since that time, and can establish to the agency's satisfaction that he or she has been providing care which permitted the individual to reside at home rather than in an institution.

(i) *Prohibition of reduction of money payments.* No money payment under another program may be reduced as a means of recovering Medicaid claims incorrectly paid.

[43 FR 45201, Sept. 29, 1978, as amended at 47 FR 43647, Oct. 1, 1982; 47 FR 49847, Nov. 3, 1982]

EDITORIAL NOTE: In § 433.36, paragraphs (a), (c), (d), (e), and (f) were revised, paragraph (g) was redesignated as paragraph (i), and new paragraphs (g) and (h) were added at 47 FR 43647, Oct. 1, 1982. The reporting and/or recordkeeping requirements contained in these paragraphs are not effective until OMB approval has been obtained.

§ 433.37 Reporting provider payments to Internal Revenue Service.

(a) *Basis and purpose.* This section based on section 1902(a)(4) of the Act, prescribes requirements concerning—

(1) Identification of providers; and

(2) Compliance with the information reporting requirements of the Internal Revenue Code.

(b) *Identification of providers.* A State plan must provide for the identification of providers by—

(1) Social security number if—

(i) The provider is in solo practice; or

(ii) The provider is not in solo practice but billing is by the individual practitioner; or

(2) Employer identification number for all other providers.

(c) *Compliance with section 6041 of the Internal Revenue Code.* The plan must provide that the Medicaid agency complies with the information reporting requirements of section 6041 of the Internal Revenue Code (26 U.S.C. 6041). Section 6041 requires the filing of annual information returns showing amounts paid to providers, who are identified by name, address, and social security number or employer identification number.

§ 433.38 Interest charge on disallowed claims for FFP.

(a) *Basis and scope.* This section is based on section 1903(d)(5) of the Act, which requires that the Secretary charge a State interest on the Federal share of claims that have been disallowed but have been retained by the State during the administrative appeals process under section 1116(d) of the Act and the Secretary later recovers after the administrative appeals process has been completed. This section does not apply to—

(1) Claims that have been deferred by the Secretary and disallowed within the time limits of § 430.40 of this chapter. Deferral of claims for FFP; or

(2) Claims for expenditures that have never been paid on a grant award; or

(3) Disallowances of any claims for services furnished before October 1, 1980, regardless of the date of the claim submitted to HCFA.

(b) *General principles.* (1) HCFA will charge a State interest on FFP when—

(i) HCFA has notified the Medicaid agency under 45 CFR 74.304 that a State claim for FFP is not allowable;

(ii) The agency has appealed the disallowance to the Grant Appeals Board under 45 CFR Part 16 and has chosen to retain the FFP during the administrative appeals process in accordance with paragraph (c)(2) of this section; and

(iii)(A) The Board has made a final determination upholding part or all of the disallowance; (B) the agency has withdrawn its appeal on all or part of the disallowance; or (C) the agency has reversed its decision to retain the funds without withdrawing its appeal and the Board upholds all or part of the disallowance.

(2) If the courts overturn, in whole or in part, a Board decision that has sustained a disallowance, HCFA will return the principal and the interest collected on the funds that were disallowed, upon the completion of all judicial appeals.

(3) Unless an agency decides to withdraw its appeal on part of the disallowance and therefore returns only that part of the funds on which it has withdrawn its appeal, any decision to retain or return disallowed funds must apply to the entire amount in dispute.

(4) If the agency elects to have HCFA recover the disputed amount, it may not reverse that election.

(c) *State procedures.* (1) If the Medicaid agency has appealed a disallowance to the Board and wishes to retain the disallowed funds until the Board issues a final determination, the agency must notify the HCFA Regional Administrator in writing of its decision to do so.

(2) The agency must mail its notice to the HCFA Regional Administrator within 30 days of the date of receipt of the notice of the disallowance, as established by the certified mail receipt accompanying the notices.

(3) If the agency withdraws either its decision to retain the FFP or its appeal on all or part of the FFP or

both, the agency must notify HCFA in writing.

(4) If the agency does not notify the HCFA Regional Administrator within the time limit set forth in paragraph (c)(2) of this section, HCFA will recover the amount of the disallowed funds from the next possible Medicaid grant award to the State.

(d) *Amount of interest charged.* (1) If the agency retains funds that later become subject to an interest charge under paragraph (b) of this section, HCFA will offset from the next Medicaid grant award to the State the amount of the funds subject to the interest charge, plus interest on that amount.

(2) The interest charge is at the rate HCFA determines to be the average of the bond equivalent of the weekly 90-day Treasury bill auction rates during the period for which interest will be charged.

(e) *Duration of interest.* (1) The interest charge on the amount of disallowed FFP retained by the agency will begin on the date of the disallowance notice and end—

(i) On the date of the final determination by the Board;

(ii) On the date HCFA receives written notice from the State that it is withdrawing its appeal on all of the disallowed funds; or

(iii) If the agency withdraws its appeal on part of the funds, on (A) the date HCFA receives written notice from the agency that it is withdrawing its appeal on a specified part of the disallowed funds for the part on which the agency withdraws its appeal; and (B) the date of the final determination by the Board on the part for which the agency pursues its appeal; or

(iv) The date HCFA receives written notice from the agency that it no longer chooses to retain the funds.

(2) HCFA will not charge interest on FFP retained by an agency for more than 12 months for disallowances of FFP made between October 1, 1980 and August 13, 1981.

[48 FR 29485, June 27, 1983]

§ 433.40 Treatment of uncashed or cancelled (voided) Medicaid checks.

(a) *Purpose.* This section provides the rules to ensure that States refund the Federal portion of uncashed or cancelled (voided) checks under title XIX.

(b) *Definitions.* As used in this section—

"*Cancelled (voided) check*" means a Medicaid check issued by a State or fiscal agent which prior to its being cashed is cancelled (voided) by the State or fiscal agent, thus preventing disbursement of funds.

"*Check*" means a check or warrant that a State or local agency uses to make a payment.

"*Fiscal agent*" means an entity that processes or pays vendor claims for the Medicaid State agency.

"*Uncashed check*" means a Medicaid check issued by a State or fiscal agent which has not been cashed by the payee.

"*Warrant*" means an order by which the State agency or local agency without the authority to issue checks recognizes a claim. Presentation of a warrant by the payee to a State officer with authority to issue checks will result in release of funds due.

(c) *Refund of Federal financial participation (FFP) for uncashed checks*—(1) *General provisions.* If a check remains uncashed beyond a period of 180 days from the date it was issued; i.e., the date of the check, it will no longer be regarded as an allowable program expenditure. If the State has claimed and received FFP for the amount of the uncashed check, it must refund the amount of FFP received.

(2) *Report of refund.* At the end of each calendar quarter, the State must identify those checks which remain uncashed beyond a period of 180 days after issuance. The State agency must refund all FFP that it received for uncashed checks by adjusting the Quarterly Statement of Expenditures for that quarter. If an uncashed check is cashed after the refund is made, the State may file a claim. The claim will be considered to be an adjustment to the costs for the quarter in which the check was originally claimed. This claim will be paid if otherwise allowed by the Act and the regulations issued pursuant to the Act.

(3) If the State does not refund the appropriate amount as specified in

paragraph (c)(2) of this section, the amount will be disallowed.

(d) *Refund of FFP for cancelled (voided) checks*—(1) *General provision.* If the State has claimed and received FFP for the amount of a cancelled (voided) check, it must refund the amount of FFP received.

(2) *Report of refund.* At the end of each calendar quarter, the State agency must identify those checks which were cancelled (voided). The State must refund all FFP that it received for cancelled (voided) checks by adjusting the Quarterly Statement of Expenditures for that quarter.

(3) If the State does not refund the appropriate amount as specified in paragraph (d)(2) of this section, the amount will be disallowed.

[51 FR 36227, Oct. 9, 1986]

§ 433.45 Sources of State share of financial participation.

(a) *Public funds as the State's share.* (1) Public funds may be considered as the State's share in claiming FFP if they meet the conditions specified in paragraphs (a)(2) and (3) of this section.

(2) The public funds are appropriated directly to the State or local Medicaid agency, or transferred from other public agencies (including Indian tribes) to the State or local agency and under its administrative control, or certified by the contributing public agency as representing expenditures eligible for FFP under this section.

(3) The public funds are not Federal funds, or are Federal funds authorized by Federal law to be used to match other Federal funds.

(b) *Private donated funds as the State's share.* (1) Funds donated from private sources may be considered as the State's share in claiming FFP only if they meet the conditions specified in paragraphs (b)(2) and (b)(3) of this section.

(2) The private funds are transferred to the State or local Medicaid agency and are under its administrative control.

(3) The private funds do not revert to the donor's facility or use unless the donor is a non-profit organization, and the Medicaid agency, of its own volition, decides to use the donor's facility.

[50 FR 46664, Nov. 12, 1985]

Subpart C—Mechanized Claims Processing and Information Retrieval Systems

§ 433.110 Basis, purpose, and applicability.

(a) This subpart implements the following sections of the Act:

(1) Section 1903(a)(3) of the Act, which provides for FFP in State expenditures for the design, development, or installation of mechanized claims processing and information retrieval systems and for the operation of certain systems. Additional HHS regulations and HCFA procedures for implementing these regulations are in 45 CFR Part 74, 45 CFR Part 95, Subpart F, and Part 11, State Medicaid Manual; and

(2) Section 1903(r) of the Act, which—(i) Requires reductions in FFP otherwise due a State under section 1903(a) if a State fails to meet certain deadlines for operating a mechanized claims processing and information retrieval system or if the system fails to meet certain conditions of approval or conditions of reapproval;

(ii) Requires at least an annual Federal performance review of the mechanized claims processing and information retrieval systems; and

(iii) Allows waivers of conditions of approval, conditions of reapproval, and FFP reductions under certain circumstances.

(b) The requirements under section 1903(r) of the Act do not apply to Puerto Rico, Guam, the Virgin Islands, American Samoa and the Northern Mariana Islands.

[50 FR 30846, July 30, 1985]

§ 433.111 Definitions.

For purposes of this section:

(a) The following terms are defined at 45 CFR Part 95, Subpart F § 95.605:

"Advance Planning Document"; "Design" or "System Design"; "Development"; "Enhancement"; "Hardware"; "Installation"; "Operation"; and, "Software".

(b) "Mechanized claims processing and information retrieval system" means a system of software and hardware used to process Medicaid claims, and to retrieve and produce utilization and management information about services that is required by the Medicaid agency or Federal Government for administrative and audit purposes.

[51 FR 45330, Dec. 18, 1986]

§ 433.112 FFP for design, development, installation or enhancement of mechanized claims processing and information retrieval systems.

(a) FFP is available at 90 percent in expenditures for design, development, installation or enhancement of a mechanized claims processing and information retrieval system, if the system is approved by the Administrator.

(b) HCFA will approve the system described in the APD if the following conditions are met:

(1) HCFA determines the system is likely to provide more efficient, economical, and effective administration of the State plan.

(2) The system meets the system requirements and performance standards in Part 11 of the State Medicaid Manual, as periodically amended.

(3) The system is compatible with the claims processing and information retrieval systems used in the administration of Medicare for prompt eligibility verification and for processing claims for persons eligible for both programs.

(4) The system supports the data requirements of peer review organizations established under Part B of title XI of the Act.

(5) The State owns any software that is designed, developed, installed or improved with 90 percent FFP.

(6) The Department has a royalty-free, non-exclusive, and irrevocable license to reproduce, publish, or otherwise use and authorize others to use, for Federal government purposes, software, modifications to software, and documentation that is designed, developed, installed or improved with 90 percent FFP.

(7) The costs of the system are determined in accordance with 45 CFR 74.171.

(8) The Medicaid agency agrees in writing to use the system for the period of time specified in the advance planning document approved by HCFA or for any shorter period of time that HCFA determines justifies the Federal funds invested.

(9) The agency agrees in writing that the information in the system will be safeguarded in accordance with Subpart F, Part 431 of this subchapter.

(Secs. 1102, 1902(a)(4) and 1903(a)(3) of the Social Security Act (42 U.S.C. 1302, 1396(a)(4) and 1396(a)(3)))

[43 FR 45201, Sept. 29, 1978, as amended at 44 FR 17937, Mar. 23, 1979; 45 FR 14213, Mar. 5, 1980; 50 FR 30846, July 30, 1985; 51 FR 45330, Dec. 18, 1986]

§ 433.113 Reduction of FFP for failure to operate a system and obtain initial approval.

(a) Except as waived under § 433.130 or 433.131, FFP will be reduced as specified in paragraph (b) of this section unless the Medicaid agency has in continuous operation a mechanized claims processing and information retrieval system that meets the following conditions:

(1) The APD for the system was approved by HCFA;

(2) The system is operational by the earlier of—

(i) September 30, 1982; or

(ii) The last day of the sixth month following the date specified for operation in the State's most recently approved APD that was submitted before October 7, 1980; and

(3) The system is initially approved by the last day of the fourth quarter that begins after the date the system became operational as determined by HCFA.

(b) HCFA will reduce FFP in expenditures for compensation and training of skilled professional medical personnel and support staff under section 1903(a)(2) of the Act, and for general administration under section 1903(a)(7) of the Act, by the following increments applied separately to those two categories of expenditures:

(1) Five percentage points for the first two quarters beginning after a

deadline in paragraph (a) of this section;

(2) An additional five percentage points during each additional two-quarter period, through the quarter in which the State achieves compliance with the conditions for initial operation or initial approval of an operating system. FFP reductions will not exceed 25 percentage points for each type of reduction.

(c) The amount of FFP (determined under section 1903(a)(3)(B)) that would be available retroactively for operating a system that later receives initial approval will be reduced by HCFA by the same percentage points for the identical periods of time described in subparagraph (b)(1) of this section, until the system is initially approved. No reduction will be made after the first quarter during which the system is initially approved.

[50 FR 30847, July 30, 1985]

§ 433.114 Procedures for obtaining initial approval; notice of decision.

(a) To obtain initial approval, the Medicaid agency must inform HCFA in writing that the system meets the conditions specified in § 433.116(c) through (h).

(b) If HCFA disapproves the system, or determines that the system met requirements for initial approval on a date later than the date required under § 433.113(a)(3), the notice will include—

(1) The findings of fact upon which the determination was made; and

(2) The procedures for appeal of the determination in the context of a reconsideration of the resulting disallowance, to the Departmental Grant Appeals Board.

[50 FR 30847, July 30, 1985]

§ 433.116 FFP for operation of mechanized claims processing and information retrieval systems.

(a) Subject to § 433.113(c), FFP is available at 75 percent of expenditures for operation of a mechanized claims processing and information retrieval system approved by HCFA, from the first day of the calendar quarter after the date the system met the conditions of initial approval, as established by HCFA (including a retroactive adjustment of FFP if necessary to provide the 75 percent rate beginning on the first day of that calendar quarter).

(b) HCFA will approve the system operation if the conditions specified in paragraphs (c) through (h) of this section are met.

(c) The conditions of § 433.112(b) (1) through (4) and (7) through (9), as periodically modified under § 433.112(b)(2), must be met.

(d) The system must have been operating continuously during the period for which FFP is claimed.

(e) The system must provide individual notices, within 45 days of the payment of claims, to all or a sample group of the persons who received services under the plan.

(f) The notice required by paragraph (e) of this section—

(1) Must specify—

(i) The service furnished;

(ii) The name of the provider furnishing the service;

(iii) The date on which the service was furnished; and

(iv) The amount of the payment made under the plan for the service; and

(2) Must not specify confidential services (as defined by the State) and must not be sent if the only service furnished was confidential.

(g) The system must provide both patient and provider profiles for program management and utilization review purposes.

(h) If the State has a Medicaid fraud control unit certified under section 1903(q) of the Act and § 455.300 of this chapter, the Medicaid agency must have procedures to assure that information on probable fraud or abuse that is obtained from, or developed by, the system is made available to that unit. (See § 455.21 of this chapter for State plan requirements.)

(Secs. 1102, 1902(a)(4) and 1903(a)(3) of the Social Security Act (42 U.S.C. 1302, 1396(a)(4) and 1396(a)(3)))

[45 FR 14213, Mar. 5, 1980. Redesignated and amended at 50 FR 30847, July 30, 1985]

§ 433.117 Initial approval of replacement systems.

(a) A replacement system must meet all conditions of initial approval of a mechanized claims processing and information retrieval system.

(b) The agency must submit a APD that includes—

(1) The date the replacement system will be in operation; and

(2) A plan for orderly transition from the system being replaced to the replacement system.

(c) FFP is available at—

(1) 90 percent in expenditures for design, development, and installation in accordance with the provisions of § 433.112; and

(2) 75 percent in expenditures for operation of an approved replacement system in accordance with the provisions of § 433.116(b) through (h), from the date that the system met the conditions of initial approval, as established by HCFA.

(d) FFP is available at 75 percent in expenditures for the operation of an approved system that is being replaced (or at a reduced rate determined under § 433.120 of this subpart for a system that has been disapproved) until the replacement system is in operation and approved.

[50 FR 30847, July 30, 1985]

§ 433.119 Conditions for yearly reapproval; notice of decision.

(a) HCFA will review yearly each system operation initially approved under § 433.114 and reapprove it for FFP at 75 percent of expenditures if the following conditions are met:

(1) The system meets the conditions of § 433.112(b) (1), (3), (4), and (7) through (9).

(2) The system meets the conditions of § 433.116 (d) through (h).

(3) The system meets the performance standards for reapproval and the system requirements in Part 11 of the State Medicaid Manual as periodically amended.

(b) HCFA will issue to each Medicaid agency, by the end of the first quarter after the fiscal year of the review, a written notice informing the agency whether its system is reapproved or disapproved. If the system is disapproved, the notice will also include—

(1) HCFA's decision to reduce FFP for system operations, and the percentage to which it is reduced, beginning with the next calendar quarter;

(2) The findings of fact upon which the determination was made; and

(3) A statement that State claims in excess of the reduced FFP rate will be disallowed and that any such disallowance will be appealable to the Grant Appeals Board.

[50 FR 30847, July 30, 1985]

§ 433.120 Procedures for reduction of FFP after yearly reapproval review.

(a) If HCFA determines after the yearly review that the system no longer meets the conditions of reapproval in § 433.119, HCFA will reduce FFP for system operations for at least four quarters. However, no system will be subject to reduction of FFP for at least the first four quarters after the quarter in which the system is initially approved as eligible for 75 percent FFP.

(b) HCFA will reduce FFP in expenditures for system operations from 75 percent to no more than 70 percent and no less than 50 percent; however, HCFA will not reduce FFP by more than 10 percentage points in any four-quarter period. The percentage to which the FFP is reduced will depend primarily on the following criteria:

(1) The number of conditions judged unsatisfactory;

(2) The extent to which conditions were not met;

(3) The significance of the unsatisfactory conditions in overall mechanized claims processing and information retrieval system operations; and

(4) The actual and potential program impact attributable to the unsatisfactory conditions.

[50 FR 30848, July 30, 1985]

§ 433.121 Reconsideration of the decision to reduce FFP after the yearly review.

(a) The agency may appeal to the Departmental Grant Appeals Board, under 45 CFR Part 16, a disallowance concerning a reduction in FFP claimed for system operation caused by a disapproval of the State's MMIS. If the Board finds such a disallowance to be appropriate, the discretionary determination to reduce FFP by a particular percentage amount (instead of by a lesser percentage) is not subject to review by the Board unless the percentage reduction exceeds the range authorized by section 1903(r)(4)(B) of the Act.

(b) The decisions concerning whether to restore any FFP retroactively and the actual number of quarters for which FFP will be restored under § 433.122 of this subpart are not subject to administrative appeal to the Grant Appeals Board under 45 CFR Part 16.

(c) An agency's request for a reconsideration before the Board under paragraph (a) of this section does not delay implementation of the reduction in FFP. However, any reduction is subject to retroactive adjustment if required by the Board's determination on reconsideration.

[50 FR 30848, July 30, 1985]

§ 433.122 Reapproval of a disapproved system.

When FFP has been reduced under § 433.120(a), and HCFA determines upon subsequent yearly review that the system meets all current performance standards, system requirements and other conditions of reapproval, the following provisions apply:

(a) HCFA will resume FFP in expenditures for system operations at the 75 percent level beginning with the quarter following the yearly review determination that the system again meets the conditions of reapproval.

(b) HCFA may retroactively waive a reduction of FFP in expenditures for system operations if HCFA determines that the waiver could improve the administration of the State Medicaid plan. However, HCFA cannot waive this reduction for any quarter before the fourth quarter immediately preceding the quarter in which HCFA issues the determination (as part of the yearly review process) stating that the system is reapproved.

[50 FR 30848, July 30, 1985]

§ 433.123 Notification of changes in system requirements, performance standards or other conditions for approval or reapproval.

(a) Whenever HCFA modifies system requirements or other conditions for approval under § 433.112 or § 433.116, or performance standards or other conditions of reapproval under § 433.119, HCFA will—

(1) Publish a notice in the FEDERAL REGISTER making available the proposed changes for public comment;

(2) Respond in a subsequent FEDERAL REGISTER notice to comments received; and

(3) Issue the new or modified standards or conditions in the State Medicaid Manual.

(b) For changes in system requirements or other conditions for approval, HCFA will allow an appropriate period for Medicaid agencies to meet the requirement determining this period on the basis of the requirement's complexity and other relevant factors.

(c) For performance standards and other conditions for reapproval, HCFA will notify Medicaid agencies at least one calendar quarter before the review period to which the new or modified standards or conditions apply.

[50 FR 30848, July 30, 1985]

§ 433.127 Termination of FFP for failure to provide access to claims processing and information retrieval systems.

HCFA will terminate FFP at any time if the Medicaid agency fails to provide State and Federal representatives with full access to the system, including on-site inspection. HCFA may request such access at any time to determine whether the conditions in this subpart are being met.

[43 FR 45201, Sept. 29, 1978. Redesignated and amended at 50 FR 30847 and 30848, July 30, 1985]

§ 433.130 Waiver of conditions of initial operation and approval.

(a) HCFA will waive requirements for initial operation and approval of systems under § 433.113 for a State meeting the requirements of paragraph (b) of this section and that had a 1976 population of less than one million and made total Federal and State Medicaid expenditures of less than $100 million in fiscal year 1976. Population figures are those reported by the Bureau of the Census. Expenditures for fiscal year 1976 are those reported by the State for that year.

(b) To be eligible for this waiver, the agency must submit its reasons to HCFA in writing and demonstrate to HCFA's satisfaction that an MMIS will not significantly improve the efficiency of the administration of the State plan.

(c) If HCFA denies the waiver request, the notice of denial will include—

(1) The findings of fact upon which the denial was made; and

(2) The procedures for appeal of the denial.

(d) If HCFA determines, after granting a waiver, that an MMIS would significantly improve the administration of the State Medicaid program, HCFA may withdraw the waiver and require that a State obtain initial approval of an MMIS within two years of the date of waiver withdrawal.

[50 FR 30848, July 30, 1985]

433.131 Waiver for noncompliance with conditions of approval and reapproval.

If a State is unable to comply with the conditions of approval or of reapproval and the noncompliance will cause a percentum reduction in FFP, HCFA will waive the FFP reduction in the following circumstances:

(a) *Good cause.* If HCFA determines that good cause existed, HCFA will waive the FFP reduction attributable to those items for which the good cause existed. A waiver of FFP consequences of the failure to meet the conditions of approval or reapproval based upon good cause will not extend beyond two consecutive quarters.

(b) *Circumstances beyond the control of a State.* The State must satisfactorily explain the circumstances that are beyond its control. When HCFA grants the waiver, HCFA will also defer all other MMIS deadlines for the same length of time that the waiver applies.

[50 FR 30848, July 30, 1985]

Subpart D—Third Party Liability

Source: 45 FR 8984, Feb. 11, 1980, unless otherwise noted.

§ 433.135 Basis and purpose.

This subpart implements sections 1902(a)(25), 1902(a)(45), 1903(d)(2), 1903(o), 1903(p), and 1912 of the Act by setting forth State plan requirements concerning—

(a) The legal liability of third parties to pay for services provided under the plan;

(b) Assignment to the State of an individual's rights to third party payments; and

(c) Cooperative agreements between the Medicaid agency and other entities for obtaining third party payments.

[50 FR 46664, Nov. 12, 1985]

§ 433.136 Definitions.

For purposes of this subpart—

Private insurer means:

(1) Any commercial insurance company offering health or casualty insurance to individuals or groups (including both experience-rated insurance contracts and indemnity contracts);

(2) Any profit or nonprofit prepaid plan offering either medical services or full or partial payment for services included in the State plan; and

(3) Any organization administering health or casualty insurance plans for professional associations, unions, fraternal groups, employer-employee benefit plans, and any similar organization offering these payments or services, including self-insured and self-funded plans.

Third party means any individual, entity or program that is or may be liable to pay all or part of the expenditures for medical assistance furnished under a State plan.

Title IV-D agency means the organizational unit in the State that has the responsibility for administering or supervising the administration of a State plan for child support enforcement under title IV-D of the Act.

[49 FR 8984, Feb. 11, 1980, as amended at 50 FR 46664, Nov. 12, 1985; 50 FR 49389, Dec. 2, 1985]

§ 433.137 State plan requirements.

(a) A State plan must provide that the requirements of §§ 433.138 and 433.139 are met for determining legal liability of third parties to pay for services under the plan and for payment of claims involving third parties.

(b) A State plan must provide that, for medical assistance furnished on or after October 1, 1984—

(1) The requirements of §§ 433.145 through 433.148 are met for assignment of rights to benefits and cooperation with the agency in obtaining medical support or payments; and

(2) The requirements of §§ 433.151 through 433.154 are met for cooperative agreements and incentive payments for third party collections.

[50 FR 46665, Nov. 12, 1985]

§ 433.138 Determining liability of third parties.

(a) *Basic provisions.* The agency must take reasonable measures to determine the legal liability of third parties to pay for services furnished under the plan. At a minimum, such measures must include the requirements specified in paragraphs (b) through (j) of this section.

(b) *Obtaining health insurance information: Initial application and redetermination processes for Medicaid eligibility.* (1) If the Medicaid agency determines eligibility for Medicaid, it must, during the initial application and each redetermination process, obtain from the applicant or recipient such health insurance information as would be useful in identifying legally liable third party resources so that the agency may process claims under the third party liability payment procedures specified in § 433.139 (b) through (f). Health insurance information may include, but is not limited to, the name of the policy holder, his or her relationship to the applicant or recipient, the social security number (SSN) of the policy holder, and the name and address of insurance company and policy number.

(2) If Medicaid eligibility is determined by the Federal agency administering the supplemental security income program under title XVI in accordance with a written agreement under section 1634 of the Act, the Medicaid agency must take the following action. It must enter into an agreement with HCFA or must have, prior to February 1, 1985, executed a modified section 1634 agreement that is still in effect to provide for—

(i) Collection, from the applicant or recipient during the initial application and each redetermination process, of health insurance information in the form and manner specified by the Secretary; and

(ii) Transmittal of the information to the Medicaid agency.

(3) If Medicaid eligibility is determined by any other agency in accordance with a written agreement, the Medicaid agency must modify the agreement to provide for—

(i) Collection, from the applicant or recipient during the initial application and each redetermination process, of such health insurance information as would be useful in identifying legally liable third party resources so that the Medicaid agency may process claims under the third party liability payment procedures specified in § 433.139(b) through (f). Health insurance information may include, but is not limited to, those elements described in paragraph (b)(1) of this section; and

(ii) Transmittal of the information to the Medicaid agency.

(c) *Obtaining other information.* The agency must, for purposes of implementing the requirements in paragraph (d)(1)(ii) and (d)(4)(i) of this section, incorporate into the eligibility case file the names and SSNs of absent or custodial parents of Medicaid recipients to the extent such information is available.

(d) *Exchange of data.* To obtain and use information for the purpose of determining the legal liability of third parties so that the agency may process claims under the third party liability payment procedures specified in § 433.139 (b) through (f), the agency must take the following actions:

(1) Except as specified in paragraph (d)(2) of this section, as part of the data exchange requirements under § 435.945 of this chapter, from the State wage information collection agency (SWICA) defined in § 435.4 of

this chapter and from the SSA wage and earnings files data as specified in § 435.948(a)(2) of this chapter, the agency must—

(i) Use the information that identifies Medicaid recipients that are employed and their employer(s); and

(ii) Obtain and use, if their names and SSNs are available to the agency under paragraph (c) of this section, information that identifies employed absent or custodial parents of recipients and their employer(s).

(2) If the agency can demonstrate to HCFA that it has an alternate source of information that furnishes information as timely, complete and useful as the SWICA and SSA wage and earnings files in determining the legal liability of third parties, the requirements of paragraph (d)(1) of this section are deemed to be met.

(3) The agency must request, as required under § 435.948(a)(6)(i), from the State title IV-A agency, information not previously reported that identifies those Medicaid recipients that are employed and their employer(s).

(4) Except as specified in paragraph (d)(5) of this section, the agency must attempt to secure agreements (to the extent permitted by State law) to provide for obtaining—

(i) From State Workers' Compensation or Industrial Accident Commission files, information that identifies Medicaid recipients and, (if their names and SSNs were available to the agency under paragraph (c) of this section) absent or custodial parents of Medicaid recipients with employment-related injuries or illnesses; and

(ii) From State Motor Vehicle accident report files, information that identifies those Medicaid recipients injured in motor vehicle accidents, whether injured as pedestrians, drivers, passengers, or bicyclists.

(5) If unable to secure agreements as specified in paragraph (d)(4) of this section, the agency must submit documentation to the regional office that demonstrates the agency made a reasonable attempt to secure these agreements. If HCFA determines that a reasonable attempt was made, the requirements of paragraph (d)(4) of this section are deemed to be met.

(e) *Diagnosis and trauma code edits.* With the exception of code 994.6, the agency must take action to identify those paid claims for Medicaid recipients that contain diagnosis codes 800 through 999 (ICDCM) International Classification of Disease. 9th Revision, Clinical Modification, Volume 1) inclusive, for the purpose of determining the legal liability of third parties so that the agency may process claims under the third party liability payment procedures specified in § 433.139 (b) through (f).

(f) *Data exchanges and trauma code edits: Frequency.* The agency must coduct the data exchange required in paragraph (d)(1) of this section in accordance with the intervals specified in § 435.948 of this chapter, the data exchanges required in paragraph (d)(3) of this section on a timely basis that is consistent with the intervals specified in § 435.948 of this chapter; and must conduct the data exchanges and diagnosis and trauma edits required in paragraphs (d)(4) and (e) of this section on a routine and timely basis. The State plan must specify the frequency of these activities.

(g) *Followup procedures for identifying legally liable third party resources*—(1) *SWICA, SSA wage and earnings files, and title IV-A data exchanges.* With respect to information obtained under paragraphs (d)(1) through (d)(3) of this section—

(i) Except as specified in § 435.952(d) of this chapter, within 30 days, the agency must followup (if appropriate) on such information in order to identify legally liable third party resources and incorporate such information into the eligibility case file and into its third party data base and third party recovery unit so the agency may process claims under the third party liability payment procedures specified in § 433.139 (b) through (f); and

(ii) The State plan must describe the methods the agency uses for meeting the requirements of paragraph (g)(1)(i) of this section.

(2) *Health insurance information and workers' compensation data exchanges.* With respect to information obtained under paragraphs (b) and (d)(4)(i) of this section—

(i) Within 60 days, the agency must followup on such information (if appropriate) in order to identify legally liable third party resources and incorporate such information into the eligibility case file and into its third party data base and third party recovery unit so the agency may process claims under the third party liability payment procedures specified in § 433.139 (b) through (f); and

(ii) The State plan must describe the methods the agency uses for meeting the requirements of paragraph (g)(2)(i) of this section.

(3) *State motor vehicle accident report file data exchanges.* With respect to information obtained under paragraph (d)(4)(ii) of this section—

(i) The State plan must describe the methods the agency uses for following up on such information in order to identify legally liable third party resources so the agency may process claims under the third party liability payment procedures specified in § 433.139 (b) through (f);

(ii) After followup, the agency must incorporate all information that identifies legally liable third party resources into the eligibility case file and into its third party data base and third party recovery unit; and

(iii) The State plan must specify timeframes for incorporation of the information.

(4) *Diagnosis and trauma code edits.* With respect to the paid claims identified under paragraph (e) of this section—

(i) The State plan must describe the methods the agency uses to follow up on such claims in order to identify legally liable third party resources so the agency may process claims under the third party liability payment procedures specified in § 433.139 (b) through (f) (Methods must include a procedure for periodically identifying those trauma codes that yield the highest third party collections and giving priority to following up on those codes.);

(ii) After followup, the agency must incorporate all information that identifies legally liable third party resources into the eligibility case file and into its third party data base and third party recovery unit; and

(iii) The State plan must specify the timeframes for incorporation of the information.

(h) *Obtaining other information and data exchanges: Safeguarding information.* (1) The agency must safeguard information obtained from and exchanged under this section with other agencies in accordance with the requirements set forth in Part 431, Subpart F of this chapter.

(2) Before requesting information from, or releasing information to other agencies to identify legally liable third party resources under paragraph (d) of this section the agency must execute data exchange agreements with those agencies. The agreements, at a minimum, must specify—

(i) The information to be exchanged;

(ii) The titles of all agency officials with the authority to request third party information;

(iii) The methods, including the formats to be used, and the timing for requesting and providing the information;

(iv) The safeguards limiting the use and disclosure of the information as required by Federal or State law or regulations; and

(v) The method the agency will use to reimburse reasonable costs of furnishing the information if payment is requested.

(i) *Reimbursement.* The agency must, upon request, reimburse an agency for the reasonable costs incurred in furnishing information under this section to the Medicaid agency.

(j) *Reports.* The agency must provide such reports with respect to the data exchanges and trauma code edits set forth in paragraphs (d)(1) through (d)(4) and paragraph (e) of this section, respectively, as the Secretary prescribes for the purpose of determining compliance under § 433.138 of the regulations and evaluating the effectiveness of the third party liability identification system.

[52 FR 5975, Feb. 27, 1987]

§ 433.139 Payment of claims.

(a) *Basic provisions.* (1) For claims involving third party liability that are processed on or after May 12, 1986, the agency must use the procedures specified in paragraphs (b) through (f) of this section.

(2) The agency must submit documentation of the methods (e.g., cost avoidance, pay and recover later) it uses for payment of claims involving third party liability to the HCFA Regional Office.

(b) *Probable liability is established at the time claim is filed.* Unless the agency has received approval to use an alternative method of payment as specified under paragraph (b)(2) of this section, the agency must pay claims involving probable third party liability as follows:

(1) If the agency has established the probable existence of third party liability at the time the claim is filed, the agency must reject the claim and return it to the provider for a determination of the amount of liability. The establishment of third party liability takes place when the agency receives confirmation from the provider or a third party resource indicating the extent of third party liability. When the amount of liability is determined, the agency must then pay the claim to the extent that payment allowed under the agency's payment schedule exceeds the amount of the third party's payment.

(2) The agency may pay the full amount allowed under the agency's payment schedule for the claim and then seek reimbursement from any liable third party to the limit of legal liability if it has obtained approval of a waiver of the requirement under paragraph (b)(1) of this section. The waiver must be in accordance with the provisions of paragraph (e) of this section.

(c) *Probable liability is not established or benefits are not available at the time claim is filed.* If the probable existence of third party liability cannot be established or third party benefits are not available to pay the recipient's medical expenses at the time the claim is filed, the agency must pay the full amount allowed under the agency's payment schedule.

(d) *Recovery of reimbursement.* (1) If the agency has an approved waiver under paragraph (e) of this section to pay a claim in which the probable existence of third party liability has been established and then seek reimbursement, the agency must seek recovery of reimbursement from the third party to the limit of legal liability within 60 days after the end of the month in which payment is made.

(2) If the agency learns of the existence of a liable third party after a claim is paid, or benefits become available from a third party after a claim is paid, the agency must seek recovery of reimbursement within 60 days after the end of the month it learns of the existence of the liable third party or benefits become available.

(3) Reimbursement must be sought unless the agency determines that recovery would not be cost effective in accordance with paragraph (f) of this section.

(e) *Waiver of required use of cost avoidance method.* (1) The requirement to use the claims payment method specified under paragraph (b)(1) of this section may be waived if—

(i) The agency is using the method of paying the entire claim and then seeking reimbursement from any liable third party as of November 12, 1985;

(ii) The agency submits adequate documentation that its method is as cost effective as the method required under paragraph (b)(1) of this section to the HCFA Regional Office on or before January 13, 1986 and requests approval of its use (Administrative costs must be considered in the computation of the cost effectiveness of the State's alternative method); and

(iii) The HCFA Regional Office approves the State's request for a waiver of the requirement.

(2) The HCFA Regional Office will review a State's request to have the requirement under paragraph (b)(1) of this section waived and notify the State of its determination within 30 days of receipt of a request. The Regional Office will request additional information from the State, if necessary.

(3) The HCFA Regional Office will grant the waiver for an indefinite period unless it specifies otherwise in the approval notice to the State. A State that is granted a waiver must

notify the Regional Office of any event that occurs that changes the cost effectiveness of the approved alternative method. The Regional Office may rescind the waiver at any time that the State's method is no longer as cost effective as the method required under paragraph (b)(1) of this section. If the waiver request is denied or the waiver is rescinded, the State has 6 months from the date of the denial or rescission notice to implement the method required under paragraph (b)(1) of this section.

(f) *Suspension or termination of recovery of reimbursement.* (1) An agency must seek reimbursement from a liable third party on all claims for which it determines that the amount it reasonably expects to recovery will be greater than the cost of recovery. Recovery efforts may be suspended or terminated only if they are not cost effective.

(2) The State plan must specify the threshold amount or other guideline that the agency uses in determining whether to seek recovery of reimbursement from a liable third party, or describe the process by which the agency determines that seeking recovery of reimbursement would not be cost effective.

(3) The State plan must also specify the dollar amount or period of time for which it will accumulate billings with respect to a particular liable third party in making the decision whether to seek recovery of reimbursement.

[50 FR 46665, Nov. 12, 1985, as amended at 51 FR 16319, May 2, 1986]

§ 433.140 FFP and repayment of Federal share.

(a) FFP is not available in Medicaid payments if—

(1) The agency failed to fulfill the requirements of §§ 433.138 and 433.139 with regard to establishing liability and seeking reimbursement from a third party;

(2) The agency received reimbursement from a liable third party; or

(3) A private insurer would have been obligated to pay for the service except that its insurance contract limits or excludes payments if the individual is eligible for Medicaid.

(b) FFP is available at the 50 percent rate for the agency's expenditures in carrying out the requirements of this subpart.

(c) If the State receives FFP in Medicaid payments for which it receives third party reimbursement, the State must pay the Federal government a portion of the reimbursement determined in accordance with the FMAP for the State. This payment may be reduced by the total amount needed to meet the incentive payment in § 433.153.

ASSIGNMENT OF RIGHTS TO BENEFITS

§ 433.145 Assignment of rights to benefits—State plan requirements.

For medical assistance furnished on or after October 1, 1984—

(a) A State plan must provide that, as a condition of eligibility, each legally able applicant and recipient must assign his rights to medical support or other third party payments to the Medicaid agency and cooperate with the agency in obtaining medical support or payments.

(b) A State plan must provide that the requirements for assignments and cooperation in establishing paternity and obtaining support under §§ 433.146 through 433.148 are met.

(c) A State plan must provide that the assignment of rights to benefits obtained from an applicant or recipient is effective only for services that are reimbursed by Medicaid.

[50 FR 46665, Nov. 12, 1985; 50 FR 49389, Dec. 2, 1985]

§ 433.146 Rights assigned; assignment method.

(a) Except as specified in paragraph (b) of this section, the agency must require the individual to assign to the State—

(1) His own rights to any medical care support available under an order of a court or an administrative agency, and any third party payments for medical care; and

(2) The rights of any other individual eligible under the plan, for whom he can legally make an assignment.

(b) Assignment of rights to benefits may not include assignment of rights to Medicare benefits.

(c) If assignment of rights to benefits is automatic because of State law, the agency may substitute such an assignment for an individual executed assignment, as long as the agency informs the individual of the terms and consequences of the State law.

§ 433.147 Cooperation in establishing paternity and obtaining support.

(a) *Scope of requirement.* The agency must require the individual who assigns his rights to cooperate in—

(1) Establishing paternity of a child born out of wedlock for whom he can legally assign rights; and

(2) Obtaining medical care support and payments for himself and any other individual for whom he can legally assign rights.

(b) *Essentials of cooperation.* As part of a cooperation, the agency may require an individual to—

(1) Appear at a State or local office designated by the agency to provide information or evidence relevant to the case;

(2) Appear as a witness at a court or other proceeding;

(3) Provide information, or attest to lack of information, under penalty of perjury;

(4) Pay to the agency any support or medical care funds received that are covered by the assignment of rights; and

(5) Take any other reasonable steps to assist in establishing paternity and securing medical support and payments.

(c) *Waiver of cooperation for good cause.* The agency must waive the requirements in paragraphs (a) and (b) of this section if it determines that the individual has good cause for refusing to cooperate.

(1) With respect to establishing paternity of a child born out of wedlock or obtaining medical care support and payments for a child for whom the individual can legally assign rights, the agency must find that cooperation is against the best interests of the child, in accordance with factors specified for the Child Support Enforcement Program at 45 CFR Part 232. If the State title IV-A agency has made a finding that good cause for refusal to cooperate does or does not exist, the Medicaid agency must adopt that finding as its own for this purpose.

(2) With respect to obtaining medical care support and payments for an individual in any case not covered by paragraph (c)(1) of this section, the agency must find that cooperation is against the best interests of the individual or other person to whom Medicaid is being furnished, because it is anticipated that cooperation will result in reprisal against, and cause physical or emotional harm to, the individual or other person.

(d) *Procedure for waiving cooperation.* With respect to establishing paternity or obtaining medical care support and payments for a child for whom the individual can legally assign rights, the agency must use the procedures specified for the Child Support Enforcement Program at 45 CFR Part 232. With respect to obtaining medical care support and payments for any other individual, the agency must adopt procedures similar to those specified in 45 CFR Part 232, excluding those procedures applicable only to children.

§ 433.148 Denial or termination of eligibility.

In administering the assignment of rights provision, the agency must:

(a) Deny or terminate eligibility for any applicant or recipient who—

(1) Refuses to assign his own rights or those of any other individual for whom he can legally make an assignment; or

(2) Refuses to cooperate as required under § 433.147(a) unless cooperation has been waived;

(b) Provide Medicaid to any individual who—

(1) Cannot legally assign his own rights; and

(2) Would otherwise be eligible for Medicaid but for the refusal, by a person legally able to assign his rights, to assign his rights or to cooperate as required by this subpart; and

(c) In denying or terminating eligibility, comply with the notice and hearing requirements of Part 431, Subpart E of this subchapter.

COOPERATIVE AGREEMENTS AND INCENTIVE PAYMENTS

§ 433.151 Cooperative agreements and incentive payments—State plan requirements.

For medical assistance furnished on or after October 1, 1984—

(a) A State plan must provide for entering into written cooperative agreements for enforcement of rights to and collection of third party benefits with at least one of the following entities: The State title IV-D agency, any appropriate agency of any State, and appropriate courts and law enforcement officials. The agreements must be in accordance with the provisions of § 433.152.

(b) A State plan must provide that the requirements for making incentive payments and for distributing third party collections specified in §§ 433.153 and 433.154 are met.

[50 FR 46665, Nov. 12, 1985; 50 FR 49389, Dec. 2, 1985]

§ 433.152 Requirements for cooperative agreements for third party collections.

(a) Except as specified in paragraph (b) of this section, the State agency may develop the specific terms of cooperative agreements with other agencies as it determines appropriate for individual circumstances.

(b) Agreements with title IV-D agencies must specify that the Medicaid agency will—

(1) Meet the requirements of the Office of Child Support Enforcement for cooperative agreements under 45 CFR Part 306; and

(2) Provide reimbursement to the IV-D agency only for those child support services performed that are not reimbursable by the Office of Child Support Enforcement under title IV-D of the Act and that are necessary for the collection of amounts for the Medicaid program.

[50 FR 46666, Nov. 12, 1985]

§ 433.153 Incentive payments to States and political subdivisions.

(a) *When payments are required.* The agency must make an incentive payment to a political subdivision, a legal entity of the subdivision such as a prosecuting or district attorney or a friend of the court, or another State that enforces and collects medical support and payments for the agency.

(b) *Amount and source of payment.* The incentive payment must equal 15 percent of the amount collected, and must be made from the Federal share of that amount.

(c) *Payment to two or more jurisdictions.* If more than one State or political subdivision is involved in enforcing and collecting support and payments:

(1) The agency must pay all of the incentive payment to the political subdivision, legal entity of the subdivision, or another State that collected medical support and payments at the request of the agency.

(2) The political subdivision, legal entity or other State that receives the incentive payment must then divide the incentive payment equally with any other political subdivisions, legal entities, or other States that assisted in the collection, unless an alternative allocation is agreed upon by all jurisdictions involved.

§ 433.154 Distribution of collections.

The agency must distribute collections as follows—

(a) To itself, an amount equal to State Medicaid expenditures for the individual on whose right the collection was based.

(b) To the Federal Government, the Federal share of the State Medicaid expenditures, minus any incentive payment made in accordance with § 433.153.

(c) To the recipient, any remaining amount. This amount must be treated as income or resources under Part 435 or Part 436 of this subchapter, as appropriate.

Subpart E—Reduction in Total Federal Payments to the States for Fiscal Years 1982–1984

§ 433.201 Statutory basis and scope.

(a) *Basis.* Sections 1903 (s) and (t) of the Act (as enacted by section 2161 of Pub. L. 97-35 and amended by section 137(b) of Pub. L. 97-248) provide for progressive reductions in Federal payments to the States, in fiscal years 1982 through 1984.

(b) *Scope.* The reductions apply only to the 49 States with Medicaid programs in operation under State plans approved by HCFA as of July 1, 1981, and to the District of Columbia. Special funding provisions in § 433.10 apply to Puerto Rico, Guam, the Virgin Islands, the Northern Mariana Islands and American Samoa.

[47 FR 43348, Sept. 30, 1982]

§ 433.203 Definitions.

For purposes of this subpart—

Abuse means provider practices that are inconsistent with sound fiscal, business or medical practices, and result in unnecessary cost to the Medicaid program, or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care.

Diverted funds means program funds not spent because claims were denied or reduced in amount as a result of the following:

(1) Procedures under § 431.54(e) of this chapter that restrict recipients, on an individual basis as distinct from a class or recipients, to obtain Medicaid services or items from designated providers.

(2) Exclusion or suspension from participation in Medicaid, or termination of agreements, of providers engaging in fraudulent or abusive practices.

(3) Use in claims processing systems of prepayment screens that are—

(i) Applied to all or a particular portion of the claims submitted by a provider specifically identified for monitoring with respect to possible fraud or abuse; or

(ii) Specifically designed to detect fraud or abuse and applied to all claims submitted by all providers or by a general category of providers.

Fraud means an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or herself or to some other person or entity. It includes any act that constitutes fraud under applicable State law.

Recoveries means amounts, incorrectly paid to providers of services under title XIX of the Act, applicable regulations and the State plan, that are actually collected, or amounts diverted by a State agency or Medicaid fraud control unit. The amounts must have been reported to the Federal government and may not include fines, penalties and unexecuted judgements established by Federal, State or local courts or administrative bodies.

Third party means any individual, entity or program that is or may be liable to pay all or part of the medical costs of injury, disease or disability of an applicant or recipient.

Third party liability means payment resources, available from both private and public health insurance, and other liable third parties, that can be applied toward Medicaid recipients' medical and health benefit expenses.

[46 FR 48001, Sept. 30, 1981; 46 FR 54744, Nov. 4, 1981, as amended at 47 FR 43348, Sept. 30, 1982]

§ 433.205 Reductions in total Federal payments.

(a) *Amount of the reductions.* HCFA will reduce total Federal payments to which a State is otherwise entitled under the Medicaid program by the following percentages:

(1) Three percent in fiscal year 1982.

(2) Four percent in fiscal year 1983.

(3) Four and one half percent in fiscal year 1984.

(b) *Effective date and date reductions end.* HCFA will impose the reductions effective October 1, 1981 for the first quarter in fiscal year 1982. No reductions will be imposed for quarters after the last quarter of fiscal year 1984, which ends on September 30, 1984. However, adjustments relating to the final computations for fiscal years 1982-1984 expenditures will continue to be made until the States have submitted all expenditure reports and all outstanding issues have been resolved.

(c) *Amounts not affected by reductions.* HCFA will not apply the progressive reductions to—

(1) Payments to a State for expenditures made before fiscal year 1982;

(2) Supplementary payments made to a State resulting from its having incurred fewer expenditures than its target amount, described in § 433.217;

(3) Payments to a State under § 433.10(c)(2) of this part for services provided through Indian Health Service facilities; or

(4) Payments to a State under Subpart D of Part 455 of this chapter for a State Medicaid fraud control unit.

[46 FR 48001, Sept. 30, 1981, as amended at 47 FR 43348, Sept. 30, 1982]

§ 433.207 Offsets against reductions.

HCFA will decrease the reduction specified in § 433.205 by one percentage point for a quarter for a State, for each of the following three conditions that the State meets:

(a) *Hospital cost review program.* Operation by the State of a hospital cost review program that meets the criteria, described in § 433.209, for the quarter covered by the Federal payment.

(b) *Unemployment levels.* An unemployment rate in the State, for the quarter before the quarter covered by the Federal payment, that is equal to or greater than 150 percent of the national unemployment rate for the same period, as determined by the Bureau of Labor Statistics.

(c) *Fraud and abuse and third party liability recoveries.* For the quarter before the quarter covered by a Federal payment, recovery through antifraud and abuse initiatives, described in § 433.213, of an amount equal to one percent of the Federal payment due to the State in that previous quarter. During fiscal year 1982 only, this total may include recoveries from liable third parties (see § 433.215).

[46 FR 48001, Sept. 30, 1981, as amended at 47 FR 43349, Sept. 30, 1982]

§ 433.209 Qualifications for offset based on hospital cost review programs.

(a) A state has a qualified hospital cost review program if the qualifications in the following paragraph (b) of this section are met.

(b) The State must provide HCFA with assurances of equitable treatment, under the State's cost review program, for hospital employees and patients, and for all payers, including Federal and State programs, that pay hospitals for inpatient hospital services. In addition, in order to qualify, a hospital cost review program must—

(1) Be established by statute;

(2) Have been in effect on July 1, 1981 and at the beginning of the quarter covered by the Federal payment;

(3) Be directly operated by the State;

(4) Apply to substantially all non-Federal acute care hospitals in the State;

(5) Provide for review of all non-Medicare revenues or expenses for inpatient hospital services, or at least 75 percent of all revenues or expenses for inpatient hospital services including those under Medicare; and

(6) Result in an annual rate of increase in aggregate hospital inpatient costs per capita, or per admission, in the State that is at least two percentage points less than the rate of increase in all States without qualifying programs. A State may meet this requirement based on performance during the most recent one, two, or three year period ending at least nine months before the quarter covered by the Federal payment.

(Approved by the Office of Management and Budget under control number 0938-0067)

[46 FR 48001, Sept. 30, 1981, as amended at 47 FR 43349, Sept. 30, 1982; 49 FR 29795, July 24, 1984]

§ 433.213 Offset based on fraud and abuse recoveries.

(a) *General policy.* HCFA will decrease the reduction under § 433.205 by one percentage point for each quarter in which the State demonstrates that its total Medicaid-related antifraud and abuse recoveries (and third party liability recoveries for fiscal year

1982 only (see § 433.215)), for the quarter before the quarter covered by the Federal payment, are equal to one percent of the Federal payment due to the State in that previous quarter. For purposes of calculating the one percent, HCFA will not include in this total any supplementary payments due to a State resulting from the State's having spent less than its target amount, described in § 433.217.

(b) *Fraud and abuse recoveries.* For purposes of paragraph (a) of this section, fraud and abuse recoveries—

(1) Must be documented by the State to the satisfaction of HCFA; and

(2) May include diverted funds or funds recovered as a result of—

(i) The operation of a State Medicaid fraud control unit, as defined in Part 455, Subpart D, of this chapter;

(ii) Audit activities that are initiated as a result of a suspicion or complaint of fraud or abuse (including any amounts recovered as restitution in civil or criminal litigation resulting from these audit activities, but not including fines, penalties, unexecuted judgments established by Federal, State, or local courts or administrative bodies, or fraud and abuse uncovered through routine audits); and

(iii) State determinations of overutilization or furnishing of unnecessary care.

(c) *Time limits applicable to diverted funds.* For purposes of determining the amount of a State's anti-fraud and abuse recoveries for a fiscal year, HCFA will prorate diverted funds as follows:

(1) *Lock-in programs.* The amount of diverted funds from lock-in programs is based on the difference between an annual total of claims for an individual recipient and the total of those claims determined by the State to be proper. HCFA will prorate this amount over the period of the restriction or for a period of four quarters, whichever is shorter, beginning with the quarter after the quarter in which the recipient is restricted to a designated provider.

(2) *Suspension or termination of providers.* The amount of diverted funds based on the exclusion, suspension or termination of providers from participation in the Medicaid program is a projected amount of fraudulent or abusive claims, as determined by a statistical sample of the provider's Medicaid claims for the most recent year. HCFA will prorate this amount over the period of the provider's exclusion, suspension or termination, or for a period of four quarters, whichever is shorter.

(d) *Procedures for carrying forward fraud and abuse recoveries.* For purposes of paragraph (a) of this section, HCFA will carry forward, from one quarter to the next, the amount by which a State demonstrates that its fraud and abuse recoveries exceed one percent of the total Federal Medicaid expenditures for the quarter covered by the Federal payment.

(Approved by the Office of Management and Budget under control number 0938-0067)

[46 FR 48001, Sept. 30, 1981; 46 FR 54744, Nov. 4, 1981, as amended at 47 FR 43349, Sept. 30, 1982; 49 FR 29795, July 24, 1984]

§ 433.215 Third party liability recoveries.

(a) *Applicability in fiscal year 1982 only.* For fiscal year 1982 only, for purposes of determining whether a State is entitled to the offset under § 433.213, HCFA will add to the total Medicaid-related anti-fraud and abuse recoveries, funds saved as a result of recoveries from liable third parties under procedures described in Subpart D of this part, except as provided in paragraph (c) of this section.

(b) *Conditions for inclusion of third party liability recoveries.* For purposes of paragraph (a) of this section, HCFA will include recoveries for liable third parties if the recoveries—

(1) Can be validated by audit; and

(2) Have been reported to the Federal government.

(c) *Recoveries from the Medicare program*—(1) *General policy.* For purposes of paragraph (a) of this section, recoveries from liable third parties may not include recoveries from the Medicare program, except those based on claims paid by Medicaid because the State did not know that the individual was entitled to both Medicare and Medicaid.

(2) *Examples of excluded recoveries.* Recoveries from Medicare that are ex-

cluded are based on those cases in which the State knows, prior to the payment of a claim, that the individual is entitled to Medicare. Examples include situations in which—

(i) The State is paying Medicare premiums for the individual under State buy-in agreements or otherwise (see Subparts B and I of Part 405 of this chapter);

(ii) The individual is receiving Supplemental Security Income (SSI) benefits under title XVI of the Act; or

(iii) The State has access to or has received information from the Federal government that identifies individuals entitled to Medicare.

(Approved by the Office of Management and Budget under control number 0938-0067)

[47 FR 43349, Sept. 30, 1982, as amended at 49 FR 29795, July 24, 1984]

§ 433.217 Use of target amounts to decrease reductions.

(a) *Purpose of the target amount.* HCFA will issue supplemental grants for fiscal years 1982-1984 based on the amount by which a State's total Federal Medicaid expenditures are under the State's target amount, described in paragraph (b) of this section, for the fiscal year. However, the supplemental grant may not exceed the amount of the reduction, described in § 433.205, for the fiscal year under consideration.

(b) *Method for determining target amounts*—(1) *Fiscal year 1982.* The target amount for a State for fiscal year 1982 is 109 percent of the State's estimate of the Federal share of all Medicaid expenditures for fiscal year 1981, in the latest estimate received by HCFA central office before April 1, 1981. The estimate may not include Federal expenditures resulting from adjustments made during fiscal year 1981 based on expenditures made before October 1, 1980.

(2) *Fiscal year 1983.* HCFA will derive the target amount for each State for fiscal year 1983 by increasing or decreasing the 1982 target amounts by a percentage equal to the percentage increase of decrease for the 12-month period ending on September 30, 1983, in the index of the medical care expenditure category of the Consumer Price Index for all urban consumers (U.S. city average) published by the Bureau of Labor Statistics.

(3) *Fiscal year 1984.* HCFA will derive the target amount for each State for fiscal year 1984 by the same method used for the 1983 targets, except that the 1982 target amounts will be increased or decreased based on medical care expenditure data for the 24-month period ending on September 30, 1984.

(c) *FMAP to be used for computing Federal Share of expenditures.* For purposes of paragraphs (a) and (b) of this section, HCFA will use the FMAP in effect for fiscal year 1981 as the applicable percentage to compute the actual Federal Share of expenditures.

(d) *Exclusions from target amount determinations.* HCFA will exclude the following from each year's target amount determinations:

(1) Adjustments with respect to prior year claims (see paragraph (b)(1) of this section);

(2) Interest paid on disallowances of disputed claims;

(3) Any offset payments a State receives for spending less than its target amount in the previous year;

(4) Payments to a State under § 433.10(c)(2) of this part for services provided through Indian Health Service facilities;

(5) Payments to a State under Subpart D of Part 455 of this chapter for a State Medicaid fraud control unit; and

(6) Any reductions in Federal payments under § 433.205.

[46 FR 48001, Sept. 30, 1981, as amended at 47 FR 43349, Sept. 30, 1982]

PART 434—CONTRACTS

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AUTHORITY: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

SOURCE: 48 FR 54020, Nov. 30, 1983, unless otherwise noted.

Subpart A—General Provisions

§ 434.1 Basis and scope.

(a) *Basis.* This part is based on sections 1902(a)(4) and 1903(m) of the Act. Section 1902(a)(4) requires that the State plan provide for methods of administration that the Secretary finds necessary for proper and efficient operation of the plan. Section 1903(m)(1)(A) of the Act defines an HMO as an entity that meets the requirements of the Public Health Service (PHS) Act to be a Federally qualified HMO, or meets two specified requirements pertaining to accessibility of services and fiscal solvency. Section 1903(m)(2)(A) limits risk-basis contracts for specified health services to entities that meet the HMO definition of section 1903(m)(1)(A) and sets forth certain enrollment and other requirements that these contracts must meet as a condition for FFP. Section 1903(m)(2)(B) exempts, from the limitations of section 1903(m)(2)(A), certain specified prepayment plans that are not HMOs.

(b) *Scope.* This part sets forth the requirements for contracts with certain organizations for furnishing Medicaid services or processing or paying Medicaid claims, or enchancing the agency's capability for effective administration of the program.

[48 FR 54020, Nov. 30, 1983; 48 FR 55128, Dec. 9, 1983]

§ 434.2 Definitions.

As used in this part, unless the context indicates otherwise—

Capitation fee means the fee the agency pays periodically to a contractor for each recipient enrolled under a contract for the provision of medical services under the State plan, whether or not the recipient receives the services during the period covered by the fee.

Clinical laboratory means a facility that examines materials derived from the human body, for the purpose of providing information for the diagnosis, prevention or treatment of a disease or the assessment of a medical condition.

Contractor means any of the following entities that contract with the Medicaid agency under a State plan and in return for a payment, to process claims, to pay for or provide medical services, or to enhance the agency's capability for effective administration of the program:

(a) A fiscal agent.

(b) A health care project grant center.

(c) A private nonmedical institution.

(d) A health insuring organization.

(e) A health maintenance organization.

(f) A prepaid health plan.

(g) A clinical laboratory.

(h) A professional management service or consultant firm.

Enrolled recipient means an individual who is eligible for Medicaid and who enters into an agreement to receive services from a health maintenance organization or prepaid health plan that contracts with the agency under this part.

Federally qualified HMO means an HMO that has been determined by HCFA to be a qualified HMO under section 1310(d) of the PHS Act.

Fiscal agent means an entity that processes or pays vendor claims for the agency.

Health care projects grant center means an entity that—

(a) Is supported in whole or in part by Federal project grant financial assistance; and

(b) Provides or arranges for medical services to recipients.

Health insuring organization means an entity that—

(a) Pays for medical services provided to recipients in exchange for a premium or subscription charge paid by the agency; and

(b) Assumes an underwriting risk.

Health maintenance organization (HMO) means a public or private organization organized under State law that—

(a) Is a federally qualified HMO; or

(b) Meets the State plan's definition of an HMO.

Nonrisk means that the contractor is not at financial risk for changes in the cost or utilization of services provided for in the payment rate agreed upon at the beginning of the contract period. Under a nonrisk contract, the State agency may make retroactive adjustment during and at the end of the contract period so that the contractor is reimbursed for costs actually incurred, subject to the upper limit of payment established in § 447.362 of this chapter, or any lower limit specified in the contract.

Prepaid health plan (PHP) means an entity that provides medical services to enrolled recipients, under contract with the Medicaid agency and on the basis of prepaid capitation fees, but does not qualify as an HMO.

Private nonmedical institution means an institution (such as a child-care facility or a maternity home) that—

(a) Is not, as a matter of regular business, a health insuring organization or a community health care center;

(b) Provides medical care to its residents through contracts or other arrangements with medical providers; and

(c) Receives capitation payments from the Medicaid agency, under a nonrisk contract, for its residents who are eligible for Medicaid.

Professional management service or consultant firm means a firm that performs management services such as auditing or staff training, or carries out studies or provides consultation aimed at improving State Medicaid operations, for example, with respect to reimbursement formulas or accounting systems.

Provisional status HMO means an HMO that the State agency has determined is a provisional status Federally qualified HMO because more than 90 days have elapsed since the HMO applied to the PHS for Federal qualification and the PHS has not made a final determination. The provisional status continues until the PHS makes the final determination or the contract with the Medicaid agency is terminated, whichever occurs first.

Risk or underwriting risk means the possibility that a contractor may incur a loss because the cost of providing services may exceed the payments made by the agency to the contractor for services covered under the contract.

[48 FR 54020, Nov. 30, 1983; 48 FR 55128, Dec. 9, 1983, as amended at 52 FR 22322, June 11, 1987]

§ 434.4 State plan requirement.

If the State plan provides for contracts of the types covered by this part, the plan must also provide for meeting the applicable requirements of this part.

§ 434.6 General requirements for all contracts and subcontracts.

(a) *Contracts.* All contracts under this part must—

(1) Include provisions that define a sound and complete procurement contract, as required by 45 CFR Part 74, Appendix G;

(2) Identify the population covered by the contract;

(3) Specify any procedures for enrollment or reenrollment of the covered population;

(4) Specify the amount, duration, and scope of medical services to be provided or paid for;

(5) Provide that the agency and HHS may evaluate through inspection or other means, the quality, appropriateness and timeliness of services performed under the contract;

(6) Specify procedures and criteria for terminating the contract, including a requirement that the contractor promptly supply all information necessary for the reimbursement of any outstanding Medicaid claims;

(7) Provide that the contractor maintains an appropriate record system for services to enrolled recipients;

(8) Provide that the contractor safeguards information about recipients as required by Part 431, Subpart F of this chapter;

(9) Specify any activities to be performed by the contractor that are related to third party liability requirements in Part 433, Subpart D of this chapter;

(10) Specify which functions may be subcontracted; and

(11) Provide that any subcontracts meet the requirements of paragraph (b) of this section.

(b) *Subcontracts.* All subcontracts must be in writing and fulfill the requirements of this part that are appropriate to the service or activity delegated under the subcontract.

(c) *Continued responsibility of contractor.* No subcontract terminates the legal responsibility of the contractor to the agency to assure that all activities under the contract are carried out.

Subpart B—Contracts with Fiscal Agents, Private Nonmedical Institutions, and Health Insuring Organizations

§ 434.10 Contracts with fiscal agents.

Contracts with fiscal agents must—

(a) Meet the requirements of § 434.6;

(b) Include termination procedures that require the contractors to supply promptly all material necessary for continued operation of payment and related systems. This material includes—

(1) Computer programs;

(2) Data files;

(3) User and operation manuals, and other documentation;

(4) System and program documentation; and

(5) Training programs for Medicaid agency staff, their agents or designated representatives in the operation and maintenance of the system;

(c) Offer to the State one or both of the following options, if the fiscal agent or the fiscal agent's subcontractor has a proprietary right to material specified in paragraph (b) of this section:

(1) Purchasing the material; or

(2) Purchasing the use of the material through leasing or other means; and

(d) State that payment to providers will be made in accordance with Part 447 of this chapter.

§ 434.12 Contracts with private nonmedical institutions.

Contracts with private nonmedical institutions must—

(a) Meet the requirements of § 434.6;

(b) Specify a capitation fee based on the cost of the services provided, in accordance with the reimbursement requirements prescribed in Part 447 of this chapter; and

(c) Specify when the capitation fee must be paid.

§ 434.14 Contracts with health insuring organizations.

(a) Contracts with health insuring organizations must—

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(1) Meet the requirements of § 434.6;

(2) Specify that the capitation fee will not exceed the limits set forth under Part 447 of this chapter;

(3) Specify that, except as permitted under paragraph (b) of this section, the capitation fee paid on behalf of each recipient may not be renegotiated—

(i) During the contract period if the contract is for 1 year or less; or

(ii) More often than annually if the contract period is for more than 1 year;

(4) Specify that the capitation fee will not include any amount for recoupment of any losses suffered by the contractor for risks assumed under the same contract or a prior contract with the agency;

(5) Specify that the contractor assumes at least part of the underwriting risk and:

(i) If the contractor assumes the full underwriting risk, specify that payment of the capitation fees to the contractor during the contract period will constitute full payment by the agency for the cost of medical services provided under the contract; and

(ii) If the contractor assumes less than the full underwriting risk, specify how the risk is apportioned between the agency and the contractor;

(6) Specify whether the contractor returns to the agency part of any savings remaining after allowable costs are deducted from the capitation fees and, if savings are returned, the apportionment between the agency and the contractor;

(7) Specify the extent, if any, to which the contractor may obtain reinsurance of a portion of the underwriting risk;

(8) Specify the actuarial basis for computation of the capitation fee.

(b) The capitation fee may be renegotiated more often than annually for recipients who are not enrolled at the time of renegotiation or if the renegotiation is required by changes in Federal or State law.

Subpart C—Contracts With HMOs and PHPs: Contract Requirements

GENERAL REQUIREMENTS

§ 434.20 Basic rules.

(a) *Entities eligible for risk contracts for services specified in § 434.21.* A Medicaid agency may enter into a risk contract, for the scope of services specified in § 434.21, only with an entity that—

(1) Is a Federally qualified HMO, including a provisional status Federally qualified HMO;

(2) Meets the State plan's definition of an HMO, as specified in paragraph (c) of this section; or

(3) Is one of several entities identified in section 1903(m)(2)(B) (i), (ii) and (iii) of the Act, and considered as PHPs.

(b) *Entities eligible for other kinds of contracts.* A Medicaid agency may enter into a nonrisk contract, or a risk contract for a scope of services other than the scope specified in § 434.21, with any of the entities identified in paragraph (a) of this section, or with any other PHP.

(c) *State plan definition of HMO.* If the plan provides for risk contracts with entities that are not Federally qualified HMOs, for the services specified in § 434.21, the plan must include a State definition of an HMO. Under the definition, the HMO must meet at least the following requirements:

(1) Be organized primarily for the purpose of providing health care services.

(2) Make the services it provides to its Medicaid enrollees as accessible to them (in terms of timeliness, amount, duration, and scope) as those services are to nonenrolled Medicaid recipients within the area served by the HMO.

(3) Make provision, satisfactory to the Medicaid agency, against the risk of insolvency, and assure that Medicaid enrollees will not be liable for the HMO's debts if it does become insolvent.

(d) *Services that may be covered.* A contract with an HMO or a PHP may cover services to enrolled recipients that are not provided under the plan to nonenrolled recipients as permitted under § 440.250(g) of this chapter.

(e) *Requirements for all contracts.* For all contracts with HMOs or PHPs—

(1) The contract must meet the requirements of § 434.6;

(2) The Medicaid agency must carry out the responsibilities specified in Subpart D of this part; and

(3) The contract must provide that any cost-sharing requirements imposed for services furnished to recipients are in accordance with §§ 447.50 through 447.58 of this chapter.

ADDITIONAL REQUIREMENTS

§ 434.21 Contracts that must meet additional requirements.

(a) Unless otherwise indicated, the additional requirements set forth in §§ 434.23 through 434.38 must be met in all types of contracts with HMOs and PHPs:

(1) Nonrisk contracts;

(2) Risk comprehensive contracts; and

(3) Other risk contracts.

(b) Risk comprehensive contracts are risk contracts for furnishing comprehensive services, that is, inpatient hospital services and any of the following services, or any three or more of the following services or groups of services:

(1) Outpatient hospital services and rural health clinic services.

(2) Other laboratory and X-ray services.

(3) Skilled nursing facility (SNF) services, early and periodic screening, diagnosis and treatment (EPSDT), and family planning.

(4) Physicians' services.

(5) Home health services.

(c) Other risk contracts are risk contracts for a scope of services other than those specified in paragraph (b) of this section.

§ 434.23 Capitation fees.

The contract must specify—

(a) The actuarial basis for computation of the capitation fees; and

(b) That the capitation fees and any other payments provided for in the contract do not exceed the payment limits set forth in §§ 447.361 and 447.362 of this chapter.

§ 434.25 Coverage and enrollment.

(a) The contract must provide that—

(1) There will be an open enrollment period doing which the HMO or PHP will accept individuals who are eligible to be covered under the contract—

(i) In the order in which they apply;

(ii) Without restriction, unless authorized by the Regional Administrator; and

(iii) Up to the limits set under the contract; and

(2) Enrollment is voluntary.

(b) Risk comprehensive contracts with HMOs must also provide that the HMO will not discriminate, against individuals eligible to be covered under contract, on the basis of health status or need for health services.

§ 434.26 Composition of enrollment.

(a) *Basic rule.* Except as provided in paragraph (b) of this section, the contract must provide that Medicare beneficiaries and Medicaid recipients constitute less than 75 percent of the total enrollment of the HMO or PHP.

(b) *Exceptions*—(1) *Waiver for new HMOs with risk comprehensive contracts.* The requirement of paragraph (a) of this section may be waived for up to three years from the date the Regional Administrator determines the entity to be an HMO (as provided in § 434.71) if the HMO submits annual reports demonstrating to the Regional Administrator's satisfaction, that it is making continuous efforts and progress toward achieving compliance with paragraph (a) of this section.

(2) *Waiver for public HMOs with risk comprehensive contracts.* The Regional Administrator may approve waiver or modification of the requirement of paragraph (a) of this section, for an HMO that is owned or operated by a State, county or municipal health department or hospital, if—

(i) There are special circumstances that justify modification or waiver; and

(ii) The HMO has made and continues to make reasonable efforts to enroll individuals who are not eligible for Medicare or Medicaid.

(3) *Waiver for PHPs and for HMOs that have contracts other than risk comprehensive.* The Medicaid agency may waive the requirement of paragraph (a) of this section if the PHP or HMO requests waiver and shows good cause.

§ 434.27 Termination of enrollment.

(a) All HMO and PHP contracts must specify—

(1) The reasons for which the HMO or PHP may terminate a recipient's enrollment;

(2) That the HMO or PHP will not terminate enrollment because of an adverse change in the recipient's health; and

(3) The methods by which the HMO or PHP will assure the agency that terminations are consistent with the reasons permitted under the contract and are not due to an adverse change in the recipient's health.

(b) An HMO risk comprehensive contract must specify—

(1) That an HMO enrollee may terminate enrollment freely at any time, effective no later than the first day of the second month after the month in which he or she requests termination; and

(2) That the HMO will inform each recipient at the time of enrollment, of the right to terminate enrollment.

[48 FR 54020, Nov. 30, 1983, as amended at 53 FR 12016, Apr. 12, 1988]

§ 434.29 Choice of health professional.

The contract must allow each enrolled recipient to choose his health professional in the HMO or the PHP to the extent possible and appropriate.

§ 434.30 Emergency medical service.

If the contract covers emergency medical services, it must—

(a) Provide that all covered emergency services are available 24 hours a day and 7 days a week, either in the contractor's own facilities or through arrangements, approved by the agency, with other providers;

(b) Specify the circumstances under which the emergency services will be covered when furnished by a provider with which the contractor does not have arrangements, including at least the following circumstances:

(1) The services were needed immediately because of an injury or sudden illness; and

(2) The time required to reach the contractor's facilities, or the facilities of a provider with which the contractor has arrangements, would have meant risk of permanent damage to the recipient's health; and

(c) Specify whether it is the contractor, or the agency, that will make prompt payment for covered emergency services that are furnished by providers specified in paragraph (b) of this section.

§ 434.32 Grievance procedure.

The contract must provide for an internal grievance procedure that—

(a) Is approved in writing by the agency;

(b) Provides for prompt resolution; and

(c) Assures the participation of individuals with authority to require corrective action.

§ 434.34 Quality assurance system.

The contract must provide for an internal quality assurance system that:

(a) Is consistent with the utilization control requirement of Part 456 of this chapter;

(b) Provides for review by appropriate health professionals of the process followed in providing health services;

(c) Provides for systematic data collection of performance and patient results;

(d) Provides for interpretation of this data to the practioners; and

(e) Provides for making needed changes.

[48 FR 54013, Nov. 30, 1983; 49 FR 9173, Mar. 12, 1984]

§ 434.36 Marketing.

The contract must specify the methods by which the HMO or PHP will assure the agency that marketing plans, procedures, and materials are accurate, and do not mislead, confuse, or defraud either recipients or the agency.

[53 FR 12016, Apr. 12, 1988]

§ 434.38 Inspection and audit of HMO's financial records.

A risk comprehensive contract with an HMO must provide that the agency and the Department may inspect and audit any financial records of the HMO or its subcontractors relating to the HMO's capacity to bear the risk of potential financial losses.

Subpart D—Contracts with HMOs and PHPs: Medicaid Agency Responsibilities

§ 434.50 Proof of HMO or PHP capability.

The agency must obtain from each contractor proof of—

(a) Financial responsibility, including proof of adequate protection against insolvency; and

(b) The contractor's ability to provide the services under the contract efficiently, effectively, and economically.

[48 FR 54020, Nov. 30, 1983; 48 FR 55128, Dec. 9, 1983]

§ 434.52 Furnishing of required services.

The agency must obtain assurances from each contractor that—

(a) It furnishes the health services required by enrolled recipients as promptly as is appropriate; and

(b) The services meet the agency's quality standards.

§ 434.53 Periodic medical audits.

(a) The agency must establish a system of periodic medical audits to insure that each contractor furnishes quality and accessible health care to enrolled recipients.

(b) The system of periodic medical audits must—

(1) Provide for audits conducted at least once a year for each contractor;

(2) Identify and collect management data for use by medical audit personnel; and

(3) Provide that the data includes—

(i) Reasons for enrollment and termination; and

(ii) Use of services.

§ 434.57 Limit on payment to other providers.

The agency must ensure that, except as specified in § 434.30(b) for emergency services, no payment is made for services furnished by a provider other than the contractor, if the services were available under the contract.

§ 434.59 Continued service to recipients whose enrollment is terminated.

The agency must arrange for Medicaid services without delay for any recipient whose enrollment is terminated, unless it is terminated because of ineligibility for Medicaid.

§ 434.61 Computation of capitation fees.

The agency must determine that the capitation fees and any other payments provided for in the contract are computed on an actuarially sound basis.

§ 434.63 Monitoring procedures.

The agency must have procedures to—

(a) Monitor enrollment and termination practices; and

(b) Insure proper implementation of the contractor's grievance procedures.

§ 434.65 Services included in the State plan but not covered by the contract.

If the contract does not cover all services available under the State plan, the agency must arrange for services not included to be available and accessible. This may be done by having the contractor refer enrolled recipients to other providers or by some other means.

Subpart E—Federal Financial Participation

§ 434.70 Condition for FFP: Status of contract.

(a) FFP is available in expenditures for payments to contractors only for the periods that the contract—

(1) Meets the requirements of this part;

(2) Meets the appropriate requirements of 45 CFR Part 74; and

(3) Is in effect.

(b) HCFA may withhold FFP for any period during which—

(1) The State fails to meet the State plan requirements of this part; or

(2) Either party to a contract substantially fails to carry out the terms of the contract.

§ 434.71 Condition for FFP: Prior approval.

FFP is not available in expenditures under an HMO contract unless the agency secured prior written notice from the Regional Office, indicating that the contractor meets the definition of an HMO.

§ 434.72 Effect of a final determination that a provisional status HMO is not an HMO.

(a) FFP is available in expenditures for payments to a provisional status HMO until the Public Health Service reaches a final determination that it is not a federally qualified HMO.

(b) The Public Health Service's determination that the entity with provisional status is not an HMO is not considered final until—

(1) All administrative, but not judicial, appeal procedures are exhausted; or

(2) The time for requesting administrative review has lapsed without a request from the HMO.

§ 434.74 Costs under risk-basis contracts.

Under each contract in which the contractor assumes an underwriting risk, the total amount paid by the agency for carrying out the provisions of the contract is a medical assistance cost.

§ 434.75 Costs under no-risk contracts.

Under each contract in which the contractor assumes no underwriting risk—

(a) The amount paid by the agency for furnishing medical services to eligible recipients is a medical assistance cost; and

(b) The amount paid by the agency for the contractor's performance of other functions is an administrative cost.

§ 434.76 Costs under fiscal agent contracts.

Under each contract with a fiscal agent—

(a) The amount paid to the provider of medical services is a medical assistance cost; and

(b) The amount paid to the contractor for performing the agreed-upon functions is an administrative cost.

§ 434.78 Right to reconsideration of disallowance.

A Medicaid agency dissatisfied with a disallowance of FFP under this subpart may request and will be granted reconsideration in accordance with 45 CFR Part 16.

PART 435—ELIGIBILITY IN THE STATES, DISTRICT OF COLUMBIA, THE NORTHERN MARIANA ISLANDS, AND AMERICAN SAMOA

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AUTHORITY: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

SOURCE: 43 FR 45204, Sept. 29, 1978, unless otherwise noted.

Subpart A—Introduction, Definitions, and General Provisions

§ 435.1 Introduction.

(a) This section provides a brief explanation of Medicaid eligibility as affected by changes in the cash assistance programs under the Social Security Act.

(b) *Medicaid eligibility before enactment of Pub. L. 92-603*—(1) *Required coverage of the categorically needy.* (i) Before enactment of the Social Security Amendments of 1972 (Pub. L. 92-603, October 30, 1972), which established the Federal program of Supplemental Security Income (SSI), States were required to make all recipients of cash assistance eligible for Medicaid. Cash assistance was provided through Federally-assisted, State-administered programs to needy individuals in four categories: Those age 65 or over (title I, Old Age Assistance), the blind (title X, Aid to the Blind), the disabled (title XIV, Aid to the Permanently and Totally Disabled), and certain types of families (title IV-A, Aid to Families with Dependent Children). At State option, cash assistance to the aged, blind, and disabled could be made available under a consolidated program of Aid to the Aged, Blind, and Disabled (title XVI).

(ii) Because an eligible individual had to be both categorically related (that is, eligible as aged, blind, disabled, or a member of a family with children deprived of the support of at least one parent) and financially eligible on the basis of income and resources, recipients of cash assistance were termed categorically needy.

(2) *Optional coverage of the categorically needy.* States could elect to cover selected groups of individuals under Medicaid who were financially eligible for cash assistance but ineligible because of certain other requirements, or who did not wish to receive cash assistance. Individuals eligible under these optional coverage provisions were considered as categorically needy and were eligible for the same services provided under Medicaid to cash assistance recipients.

(3) *Coverage of the medically needy.* (i) States could limit coverage under Medicaid to the categorically needy or could, in addition, extend Medicaid to aged, blind, or disabled individuals, or members of families with dependent children, who had too much income to be eligible for cash assistance but not enough for medical care. These individuals were termed "medically needy." A State could set higher levels of income and resources for determining eligibility for Medicaid than those used in determining eligibility for cash assistance. Whether it used higher levels for the medically needy or the same level as for the categorically needy, the State had to deduct an applicant's incurred medical expenses from income in determining his eligibility for Medicaid. As a result, unlike eligibility for cash assistance, eligibility under the medically needy coverage provision did not depend solely on the absolute amount of an individual's income.

(ii) Because a State would be covering more people under the medically needy program, it was permitted to provide more limited Medicaid services to the medically needy than to the categorically needy.

(c) *Changes in cash assistance resulting from enactment of Pub. L. 92-603*—(1) *Supplemental Security Income.* Pub. L. 92-603 established a Federal program of cash benefits for the aged, blind, and disabled under a new title XVI of the Act. The SSI program, administered by the Social Security Administration, became effective January 1, 1974, and replaced the previous programs for the aged, blind, and disabled in all jurisdictions of the United States except Puerto Rico, Guam, and the Virgin Islands. In addition to establishing uniform nationwide eligibility standards and requirements, the new title expanded the definition of disability to include individuals under age 18. It also provided for State supplements to the Federal SSI benefit.

(2) *Mandatory State supplements.* In general, most individuals who had been receiving cash assistance under State programs that had used more liberal eligibility requirements than SSI were deemed to meet the new SSI requirements for purposes of Medicaid coverage. In addition, States that had been making higher payments to individuals under the previous programs of cash assistance were required to pay the difference between the SSI benefit and the previous payment. States must provide Medicaid to recipients of these mandatory State supplements.

(3) *Optional State supplementation.* States may also pay optional cash supplements either to all aged, blind, and disabled SSI recipients or only to reasonable classifications, such as the aged. Under certain conditions, States may provide Medicaid to optional supplement recipients.

(d) *Changes in Medicaid eligibility as a result of Pub. L. 92-603*—(1) *General.* In view of the projected increase in the number of individuals who would qualify for cash assistance under SSI, Pub. L. 92-603 changed the requirements for Medicaid coverage in that States are no longer required to cover all aged, blind, and disabled cash (SSI) recipients. It did not change the mandatory coverage of all AFDC recipients.

(2) *SSI option.* States may make SSI recipients eligible for Medicaid. In addition, they may provide Medicaid to individuals receiving only optional State supplements.

(3) *Restricted eligibility ("section 209(b)") option.* Section 209(b), Pub. L. 92-603 (section 1902(f) of the Act), permits States to limit Medicaid eligibility for the aged, the blind, or the disabled to individuals who meet eligibility requirements more restrictive than those under SSI. However, States exercising this option must deduct SSI, optional State supplements, and incurred medical expenses from

income in determining Medicaid eligibility.

Thus, there is no fixed income ceiling under this option; it permits any aged, blind, or disabled individual with enough medical expenses to become eligible.

(4) *Protected Medicaid eligibility.* Whichever major option for coverage of the aged, blind, or disabled a State elects, all States are required to provide Medicaid to recipients of mandatory State supplements and to certain other groups of individuals who were eligible for Medicaid in December 1973 under optional coverage provisions.

(e) *Changes in Medicaid eligibility as a result of Pub. L. 97-35*—(1) *General purposes.* The intent of this legislation is to give States more flexibility in determining which individuals will be eligible for Medicaid.

(2) *Categorically needy.* If participants of a work supplementation program are deemed to be AFDC recipients under section 414 of the Act, the State must make them eligible for Medicaid. If certain pregnant women are deemed to be AFDC recipients under section 406 of the Act, the State must make them eligible for Medicaid. The State must provide Medicaid to individuals who are denied AFDC cash payment solely because the payment would be less than $10 a month (section 402(a) of the Act). The upper age limit of AFDC dependent children has been lowered from under age 21 to under age 19.

(3) *Medically needy.* The State is no longer required to include among the medically needy all those groups formerly mandated under the statute, that is the aged, blind, disabled, and families with dependent children, who do not receive cash assistance and whose income and resources are insufficient to enable them to pay for the cost of necessary health care. Rather, the State may restrict participation in the State Medicaid program to some of those groups. However, if the State chooses to provide for medically needy under the State plan, it must provide medical assistance to individuals under age 21, or a younger age, or reasonable classifications, as determined by the State (section 1905(a)(i) of the Act), and to pregnant women who, but for income and resources, would be included among the cagetorically needy (section 1902(a)(10)(C)(ii) of the Act).

[43 FR 45204, Sept. 29, 1978, as amended at 46 FR 47984, Sept. 30, 1981]

§ 435.2 Purpose and applicability.

This part sets forth, for the 50 States, the District of Columbia, the Northern Mariana Islands, and American Samoa—

(a) The eligibility provisions that a State plan must contain;

(b) The mandatory and optional groups of individuals to whom Medicaid is provided under a State plan;

(c) The eligibility requirements and procedures that the Medicaid agency must use in determining and redetermining eligibility, and requirements it may not use;

(d) The availability of FFP for providing Medicaid and for administering the eligibility provisions of the plan; and

(e) Other requirements concerning eligibility determinations, such as use of an institutionalized individual's income for the cost of care.

[43 FR 45204, Sept. 29, 1978, as amended at 44 FR 17937, Mar. 23, 1979; 51 FR 41350, Nov. 14, 1986]

§ 435.3 Basis.

(a) This part implements the following sections of the Act and public laws which state eligibility requirements and standards.

402(a)(22) Eligibility of deemed recipients of AFDC who receive zero payments because of recoupment of overpayments.

402(a)(37) Eligibility of individuals who lose AFDC eligibility due to increased earnings.

414(g) Eligibility of certain individuals participating in work supplementation programs.

1619(b) Benefits for blind individuals or those with disabling impairments whose income equals or exceeds a specific SSI limit.

1902(a)(8) Opportunity to apply; assistance must be furnished promptly.

1902(a)(10) Required and optional groups.

1902(a)(12) Determination of blindness.

1902(a)(17) Standards for determining eligibility: flexibility in the application of income eligibility standards.

1902(a)(19) Safeguards for simplicity of administration and best interests of recipients.

1902(a)(34) Three-month retroactive eligibility.

1902(a) (second paragraph after (47)) Eligibility despite increased monthly insurance benefits under title II.

1902(b) Prohibited conditions for eligibility: Age requirement of more that 65 years;

State residence requirements excluding individuals who reside in the state; and

Citizenship requirement excluding United States citizens.

1902(e) Four-month continued eligibility for families ineligible because of increased hours or income from employment.

1902(e)(2) Minimum eligibility period for recipient enrolled in an HMO.

1902(e)(4) Eligibility of newborn children of Medicaid eligible women.

1902(f) State option to restrict Medicaid eligibility for aged, blind, or disabled individuals to those who would have been eligible under State plan in effect in January 1972.

1902(j) Medicaid program in American Samoa.

1903(f) Income limitations for medically needy and individuals covered by State supplement eligibility requirements.

1905(a) (clause following (21)) Prohibitions against providing Medicaid to certain institutionalized individuals.

1905(a) (second sentence) Definition of essential person.

1905(a)(i)-(viii) List of eligible individuals.

1905(d)(2) Definition of resident of an intermediate care facility for the mentally retarded.

1905(j) Definition of State supplementary payment.

1905(k) Eligibility of essential spouses of eligible individuals.

1905(n) Definition of qualified pregnant woman and child.

1915(c) Home or community-based services.

412(e)(5) of Immigration and Nationality Act—Eligibility of certain refugees.

Pub. L. 93-66, section 230 Deemed eligibility of certain essential persons.

Pub. L. 93-66, section 231 Deemed eligibility of certain persons in medical institutions.

Pub. L. 93-66, section 232 Deemed eligibility of certain blind and disabled medically indigent persons.

Pub. L. 93-233, section 13(c) Deemed eligibility of certain individuals receiving mandatory State supplementary payments.

Pub. L. 94-566, section 503 Deemed eligibility of certain individuals who would be eligible for supplemental security income benefits but for cost-of-living increases in social security benefits.

Pub. L. 96-272, section 310(b)(1) Continued eligibility of certain recipients of Veterans Administration pensions.

(b) This part implements the following other provisions of the Act or public laws that establish additional State plan requirements:

1618 Requirement for operation of certain State supplementation programs.

Pub. L. 93-66, section 212(a) Required mandatory minimum State supplementation of SSI benefits programs.

[52 FR 43071, Nov. 9, 1987; 52 FR 48438, Dec. 22, 1987]

§ 435.4 Definitions and use of terms.

As used in this part—

AABD means aid to the aged, blind, and disabled under title XVI of the Act;

AB means aid to the blind under title X of the Act;

AFDC means aid to families with dependent children under title IV-A of the Act;

APTD means aid to the permanently and totally disabled under title XIV of the Act;

Categorically needy means aged, blind or disabled individuals or families and children

(a) Who are otherwise eligible for Medicaid and who meet the financial eligibility requirements for AFDC, SSI, or an optional State supplement or are considered under section 1619(b) of the Act to be SSI recipients; or

(b) Whose categorical eligibility is protected by statute (e.g., persons receiving cost of living increases under § 435.135).

Families and children refers to eligible members of families with children who are financially eligible under AFDC or medically needy rules and who are deprived of parental support or care as defined under the AFDC program (see 45 CFR 233.90, 233.100). In addition, this group includes individuals under age 21 who are not deprived of parental support or care but are financially eligible under AFDC rules or medically needy rules (see optional coverage group, § 435.222). It does not include individuals under age 21 whose eligibility for Medicaid is based on blindness or disability—for these individuals, SSI rules govern;

Mandatory State supplement means a cash payment a State is required to make under section 212, Pub. L. 93-66 (July 9, 1973) to an aged, blind, or disabled individual. Its purpose is to provide an individual with the same amount of cash assistance he was receiving under OAA, AB, APTD, or AABD if his SSI payment is less than that amount;

Medically needy means aged, blind, or disabled individuals or families and children who are otherwise eligible for Medicaid, who are not categorically needy, and whose income and resources are within limits set under the Medicaid State plan;

OAA means old age assistance under title I of the Act;

OASDI means old age, survivors, and disability insurance under title II of the Act;

Optional State supplement means a cash payment made by a State, under section 1616 of the Act, to an aged, blind, or disabled individual;

SSI means supplemental security income under title XVI of the Act.

SWICA means the State Wage Information Collection Agency under section 1137(a) of the Act. It is the State agency administering the State unemployment compensation law; a separate agency administering a quarterly wage reporting system; or a State agency administering an alternative system which has been determined by the Secretary of Labor, in consultation with the Secretary of Agriculture and the Secretary of Health and Human Services, to be as effective and timely in providing employment related income and eligibility data.

[43 FR 45204, Sept. 29, 1978, as amended at 45 FR 24883, Apr. 11, 1980; 46 FR 6909, Jan. 22, 1981; 46 FR 47984, Sept. 30, 1981; 51 FR 7211, Feb. 28, 1986]

§ 435.10 State plan requirements.

A State plan must—

(a) Provide that the requirements of this part are met; and

(b) Specify the groups to whom Medicaid is provided, as specified in Subparts B, C, and D of this part, and the conditions of eligibility for individuals in those groups.

Subpart B—Mandatory Coverage of the Categorically Needy

§ 435.100 Scope.

This subpart prescribes requirements for coverage of categorically needy individuals.

MANDATORY COVERAGE OF FAMILIES AND CHILDREN

§ 435.110 Individuals receiving aid to families with dependent children.

(a) A Medicaid agency must provide Medicaid to individuals receiving AFDC.

(b) For purposes of this section, an individual is receiving AFDC if his needs are included in determining the amount of the AFDC payment. This includes an individual whose presence in the home is considered essential to the well-being of a recipient (see 45 CFR 233.20(a)(2)(vi)) and who could be a recipient under the State's AFDC plan if that plan were as broad as allowed under the Act for FFP.

§ 435.112 Families terminated from AFDC because of increased earnings or hours of employment.

(a) If a family loses AFDC solely because of increased income from employment or increased hours of employment, the agency must continue to provide Medicaid for 4 months to all members of the family if—

(1) The family received AFDC in any 3 or more months during the 6-month period immediately before the month in which it became ineligible for AFDC; and

(2) At least one member of the family is employed throughout the 4-month period, although this need not be the same member for the whole period.

(b) The 4 calendar month period begins on the date AFDC is terminated. If AFDC benefits are terminated retroactively, the 4 calendar month period also begins retroactively with the first month in which AFDC was erroneously paid.

[43 FR 45204, Sept. 29, 1978, as amended at 45 FR 24883, Apr. 11, 1980]

§ 435.113 Individuals who are ineligible for AFDC because of requirements that do not apply under title XIX of the Act.

The agency must provide Medicaid to individuals who would be eligible for AFDC except for an eligibility requirement used in that program that is specifically prohibited under title XIX.

[47 FR 43648, Oct. 1, 1982]

§ 435.114 Individuals who would be eligible for AFDC except for increased OASDI income under Pub. L. 92-336 (July 1, 1972).

The agency must provide Medicaid to individuals who meet the following conditions:

(a) In August 1972, the individual was entitled to OASDI and—

(1) He was receiving AFDC; or

(2) He would have been eligible for AFDC if he had applied, and the Medicaid plan covered this optional group; or

(3) He would have been eligible for AFDC if he were not in a medical institution or intermediate care facility, and the Medicaid plan covered this optional group.

(b) The individual would currently be eligible for AFDC except that the increase in OASDI under Pub. L. 92-336 raised his income over the limit allowed under AFDC. This includes an individual who—

(1) Meets all current AFDC requirements except for the requirement to file an application; or

(2) Would meet all current AFDC requirements if he were not in a medical institution or intermediate care facility, and the current Medicaid plan covers this optional group.

§ 435.115 Individuals deemed to be receiving AFDC.

(a) The Medicaid agency must provide Medicaid to individuals deemed to be receiving AFDC, as specified in this section.

(b) The State must deem individuals to be receiving AFDC who are denied a cash payment from the title IV-A State agency solely because the amount of the AFDC payment would be less than $10.

(c) The State may deem participants in a work supplementation program to be receiving AFDC under section 414(g) of the Act. This section permits States, for purposes of title XIX, to deem an individual and any child or relative of the individual (or other individual living in the same household) to be receiving AFDC, if the individual—

(1) Participates in a State-operated work supplementation program under section 414 of the Act; and

(2) Would be eligible for an AFDC cash payment if the individual were not participating in the work supplementation program.

(d) The State must deem to be receiving AFDC those individuals who are denied AFDC payments from the title IV-A State agency solely because that agency is recovering an overpayment.

[46 FR 47985, Sept. 30, 1981, as amended at 52 FR 43071, Nov. 9, 1987]

MANDATORY COVERAGE OF PREGNANT WOMEN, CHILDREN UNDER 5, AND NEWBORN CHILDREN

§ 435.116 Qualified pregnant women and children.

(a) The agency must provide Medicaid to a pregnant woman whose pregnancy has been medically verified and who—

(1) Would be eligible for an AFDC cash payment (or would be eligible for an AFDC cash payment if coverage under the State's AFDC plan included an AFDC-unemployed parents program) if her child had been born and was living with her in the month of payment;

(2) Is a member of a family that would be eligible for an AFDC cash payment if the State's AFDC plan included an AFDC-unemployed parents program; or

(3) Meets the income and resource requirements of the State's approved AFDC plan. In determining whether

the woman meets the AFDC income and resource requirements, the unborn child or children are considered members of the household, and the woman's family is treated as though deprivation exists.

(b) The provisions of paragraphs (a) (1) and (2) of this section are effective October 1, 1984. The provisions of paragraph (a)(3) of this section are effective July 1, 1986.

(c) The agency must provide Medicaid to children who meet all of the following criteria:

(1) They are born after September 30, 1983 or, at State option, effective no earlier than April 1, 1986, an earlier designated date;

(2) They are under 5 years of age; and

(3) They meet the income and resource requirements of the State's approved AFDC plan.

[52 FR 43071, Nov. 9, 1987]

§ 435.117 Newborn children.

(a) The agency must provide categorically needy Medicaid eligibility to a child born to a woman who is eligible as categorically needy and is receiving Medicaid on the date of the child's birth. The child is deemed to have applied and been found eligible for Medicaid on the date of birth and remains eligible as categorically needy for one year so long as the woman remains eligible as categorically needy and the child is a member of the woman's household. If the mother's basis of eligibility changes to medically needy, the child is eligible as medically needy under § 435.301(b)(1)(iii).

(b) The requirements under paragraph (a) of this section apply to children born on or after October 1, 1984.

[52 FR 43071, Nov. 9, 1987]

MANDATORY COVERAGE OF ADOPTION ASSISTANCE AND FOSTER CARE CHILDREN

§ 435.118 Children for whom adoption assistance or foster care maintenance payments are made.

The agency must provide Medicaid to children for whom adoption assistance or foster care maintenance payments are made under title IV-E of the Act.

[47 FR 28655, July 1, 1982]

MANDATORY COVERAGE OF THE AGED, BLIND, AND DISABLED

§ 435.120 Individuals receiving SSI.

(a) *General provisions.* Except as allowed under § 435.121, the agency must provide Medicaid to aged, blind, and disabled individuals or couples who receive SSI, including—

(1) Individuals receiving SSI pending a final determination of blindness or disability;

(2) Individuals receiving SSI under an agreement with the Social Security Administration to dispose of resources that exceed the SSI dollar limits on resources; and

(3) For the period beginning January 1, 1981, and ending June 30, 1987, individuals considered to be receiving SSI under section 1619(b) of the Act (blind individuals or those with disabling impairments whose income equals or exceeds a specific Supplemental Security Income limit). (Regulations at 20 CFR 416.263 through 416.269 contain requirements governing determinations of eligibility under this provision.)

(b) *Exclusion.* Individuals entitled to benefits under section 1622 of the Act are not to be considered individuals receiving SSI. Section 1622 of the Act provides for certain individuals whose minimum benefits under title II of the Act were reduced by section 2201 of Pub. L. 97-35.

[46 FR 47985, Sept. 30, 1981, as amended at 50 FR 46763, Nov. 13, 1985]

§ 435.121 Individuals in States using more restrictive requirements for Medicaid than the SSI requirements.

(a) The agency may use Medicaid eligibility requirements for the aged, blind, or disabled that are more restrictive than the eligibility requirements for SSI. The agency may be more restrictive in defining blindness or disability, more restrictive in setting financial requirements for income or resources, or both. The requirements may apply to the aged or the blind or the disabled, or to any combination. For example, the agency may use a more restrictive definition of disability for those applying for Medicaid as disabled and a more restrictive income requirement for those who apply as aged, but provide Medicaid to all individuals receiving SSI on the basis of blindness.

(b) If an agency uses more restrictive requirements under this section—

(1) Each requirement may be no more restrictive than that in effect under the State's Medicaid plan on January 1, 1972, and no more liberal than that applied under SSI or an optional State supplement program that meets the conditions of § 435.230; and

(2) In determining financial eligibility of an individual in the category to which the more restrictive requirements apply, the agency must deduct, from the individual's income, his SSI payment, any optional State supplement, and incurred medical expenses as specified in § 435.732.

(c) The following sections of this part apply to the agency's use of more restrictive eligibility requirements:

(1) Section 435.135, treatment of individuals who receive OASDI cost-of-living increases.

(2) Section 435.330, medically needy coverage.

(3) Section 435.530, more restrictive definitions of blindness.

(4) Section 435.540, more restrictive definitions of disability.

(5) Sections 435.731 through 435.733, more restrictive income and resource requirements.

(6) Sections 435.812, 435.823, 435.831, and 435.841, medically needy financial eligibility requirements.

[43 FR 45204, Sept. 29, 1978, as amended at 45 FR 24883, Apr. 11, 1980; 46 FR 47985, Sept. 30, 1981; 48 FR 39629, Sept. 1, 1983]

§ 435.122 Individuals who are ineligible for SSI or optional State supplements because of requirements that do not apply under title XIX of the Act.

If an agency provides Medicaid to aged, blind, or disabled individuals receiving SSI or optional State supplements, it must provide Medicaid to individuals who would be eligible for SSI or optional State supplements except for an eligibility requirement used in those programs that is specifically prohibited under title XIX.

[47 FR 43648, Oct. 1, 1982; 47 FR 49847, Nov. 3, 1982]

§ 435.130 Individuals receiving mandatory State supplements.

The agency must provide Medicaid to individuals receiving mandatory State supplements.

§ 435.131 Individuals eligible as essential spouses in December 1973.

(a) The agency must provide Medicaid to any person who was eligible for Medicaid in December 1973 as an essential spouse of an aged, blind, or disabled individual who was receiving cash assistance, if the conditions in paragraph (b) of this section are met. An "essential spouse" is defined in section 1905(a) of the Act as one who is living with the individual; whose needs were included in determining the amount of cash payment to the individual under OAA, AB, APTD, or AABD; and who is determined essential to the individual's well-being.

(b) The agency must continue Medicaid if—

(1) The aged, blind, or disabled individual continues to meet the December 1973 eligibility requirements of the applicable State cash assistance plan; and

(2) The essential spouse continues to meet the conditions that were in effect in December 1973 under the applicable cash assistance plan for having his needs included in computing the payment to the aged, blind, or disabled individual.

§ 435.132 Institutionalized individuals who were eligible in December 1973.

The agency must provide Medicaid to individuals who were eligible for Medicaid in December 1973, or any part of that month, as inpatients of medical institutions or residents of intermediate care facilities that were participating in the Medicaid program and who—

(a) For each consecutive month after December 1973—

(1) Continue to meet the requirements for Medicaid eligibility that were in effect under the State's plan in December 1973 for institutionalized individuals; and

(2) Remain institutionalized; and

(b) Are determined by the State or a professional standards review organization to continue to need institutional care.

§ 435.133 Blind and disabled individuals eligible in December 1973.

The agency must provide Medicaid to individuals who—

(a) Meet all current requirements for Medicaid eligibility except the criteria for blindness or disability;

(b) Were eligible for Medicaid in December 1973 as blind or disabled individuals, whether or not they were receiving cash assistance in December 1973; and

(c) For each consecutive month after December 1973, continue to meet the criteria for blindness or disability and the other conditions of eligibility used under the Medicaid plan in December 1973.

§ 435.134 Individuals who would be eligible except for the increase in OASDI benefits under Pub. L. 92-336 (July 1, 1972).

The agency must provide Medicaid to individuals who meet the following conditions:

(a) In August 1972, the individual was entitled to OASDI and—

(1) He was receiving OAA, AB, APTD, or AABD; or

(2) He would have been eligible for one of those programs except that he had not applied, and the Medicaid plan covered this optional group; or

(3) He would have been eligible for one of those programs if he were not in a medical institution or intermediate care facility, and the Medicaid plan covered this optional group.

(b) The individual would currently be eligible for SSI or a State supplement except that the increase in OASDI under Pub. L. 92-336 raised his income over the limit allowed under SSI. This includes an individual who—

(1) Meets all current SSI requirements except for the requirement to file an application; or

(2) Would meet all current SSI requirements if he were not in a medical institution or intermediate care facility, and the State's Medicaid plan covers this optional group.

[43 FR 45204, Sept. 29, 1978, as amended at 45 FR 24883, Apr. 11, 1980]

§ 435.135 Individuals who become ineligible for cash assistance as a result of OASDI cost-of-living increases received after April 1977.

(a) If an agency provides Medicaid to aged, blind, or disabled individuals receiving SSI or State supplements, it must provide Medicaid to individuals who—

(1) Are receiving OASDI;

(2) Were eligible for and receiving SSI or State supplements but became ineligible for those payments after April 1977; and

(3) Would still be eligible for SSI or State supplements if the amount of OASDI cost-of-living increases paid under section 215(i) of the Act, after the last month after April 1977 for which those individuals were both eligible for and received SSI or a State supplement and were entitled to OASDI, were deducted from current OASDI benefits.

(b) Cost-of-living increases include the increases received by the individual or his or her financially responsible spouse or other family member (e.g., a parent).

(c) If the agency adopts more restrictive eligibility requirements than those under SSI, it must provide Medicaid to individuals specified in paragraph (a) of this section on the same basis as Medicaid is provided to individuals continuing to receive SSI or State supplements. If the individual incurs enough medical expenses to reduce his or her income to the financial eligibility standard for the categorically needy, the agency must cover that individual as categorically needy. In determining the amount of his or her income, the agency may deduct the cost-of-living increases paid under section 215(i) after the last month after April 1977 for which that individual was both eligible for and received SSI or a State supplement and was entitled to OASDI, up to the amount that made him or her ineligible for SSI.

[51 FR 12330, Apr. 10, 1986]

§ 435.136 State agency implementation requirements for one-time notice and annual review system.

An agency must—

(a) Provide a one-time notice of potential Medicaid eligibility under § 435.135 to all individuals who meet the requirements of § 435.135 (a) or (c) who were not receiving Medicaid as of March 9, 1984; and

(b) Establish an annual review system to identify individuals who meet the requirements of § 435.135 (a) or (c) and who lose categorically needy eligibility for Medicaid because of a loss of SSI. States without medically needy programs must send notices of potential eligibility for Medicaid to these individuals for 3 consecutive years following their identification through the annual review system.

[51 FR 12330, Apr. 10, 1986]

Subpart C—Options for Coverage as Categorically Needy

§ 435.200 Scope.

This subpart specifies options for coverage of individuals as categorically needy.

§ 435.201 Individuals included in optional groups.

Except where otherwise specified, a Medicaid agency that chooses to cover an optional group must provide Medicaid to all eligible individuals in that group. For example, in the options applicable to families and children and the aged, blind, or disabled, the agency may not provide Medicaid only to families and children; similarly, in the options applicable to the aged, blind, or disabled, it may not cover only the blind.

OPTIONS FOR COVERAGE OF FAMILIES AND CHILDREN AND THE AGED, BLIND, AND DISABLED

§ 435.210 Individuals who would be eligible for but are not receiving cash assistance.

The agency may provide Medicaid to individuals who would be eligible for AFDC, SSI, or an optional State supplement as specified in § 435.230 but who are not receiving these benefits.

§ 435.211 Individuals who would be eligible for cash assistance except for their institutional status.

The agency may provide Medicaid to individuals in title XIX reimbursable medical institutions and intermediate care facilities who are ineligible for AFDC, SSI, or an optional State supplement because of lower income standards used under these programs to determine eligibility for institutionalized individuals, but who would be eligible for AFDC, SSI, or an optional State supplement as specified in § 435.230 if they were not institutionalized.

[45 FR 24884, Apr. 11, 1980]

§ 435.212 Individuals who would be ineligible if they were not enrolled in an HMO.

The agency may provide that a recipient who is enrolled in a federally qualified HMO (under a risk contract as specified in § 434.20(a)(1) of this chapter) and who becomes ineligible for Medicaid is deemed to continue to be eligible—

(a) For a period specified by the agency, ending no later than 6 months from the date of enrollment; but

(b) Only for benefits provided to him or her as an HMO enrollee.

[48 FR 54025, Nov. 30, 1983]

§ 435.217 Individuals receiving home and community-based services.

The agency may provide Medicaid to any group or groups of individuals in the community who—

(a) Would be eligible for Medicaid if institutionalized;

(b) Would require institutionalization in the absence of home and community-based services under a waiver granted under Part 441, Subpart G, of this subchapter; and

(c) Receive the waivered services.

[50 FR 10026, Mar. 13, 1985]

OPTIONS FOR COVERAGE OF FAMILIES AND CHILDREN

§ 435.220 Individuals who would be eligible for AFDC if child care costs were paid from earnings.

(a) The agency may provide Medicaid to individuals who would be eligible for AFDC if their work-related child care costs were paid from their earnings rather than by a State agency as a service expenditure.

(b) The agency may use this option only if the State's AFDC plan deducts work-related child care costs from income to determine the amount of AFDC.

§ 435.221 [Reserved]

§ 435.222 Individuals under age 21 who would be eligible for AFDC but do not qualify as dependent children.

(a) The agency may provide Medicaid to individuals under age 21 (or, at State option, under age 20, 19 or 18) who would be eligible for AFDC if they met the definition of dependent child. (See 45 CFR 233.90(c)(1).)

(b) The agency may cover all individuals described in paragraph (a) of this section or reasonable classifications of those individuals. Examples of reasonable classifications are as follows:

(1) Individuals in foster homes or private institutions for whom a public agency is assuming a full or partial financial responsibility. If the agency covers these individuals, it may also provide Medicaid to individuals of the same age placed in foster homes or private institutions by private nonprofit agencies.

(2) Individuals in adoptions subsidized in full or in part by a public agency.

(3) Individuals in intermediate care facilities, if intermediate care facility services are provided under the plan. If the agency covers these individuals, it may also provide Medicaid to individuals in intermediate care facilities for the mentally retarded.

(4) Individuals under age 21 receiving active treatment as inpatients in pyschiatric facilities or programs, if inpatient psychiatric services for individuals under 21 are provided under the plan.

[46 FR 47985, Sept. 30, 1981; 46 FR 54743, Nov. 4, 1981]

§ 435.223 Individuals who would be eligible for AFDC if coverage under the State's AFDC plan were as broad as allowed under title IV-A.

(a) The agency may provide Medicaid to individuals who—

(1) Would be eligible for AFDC if the State's AFDC plan included individuals whose coverage under Title IV-A is optional (for example, Medicaid may be provided to members of families with an unemployed parent even though AFDC is not available to them under the State's AFDC plan); or

(2) Would be eligible for AFDC if the State's AFDC plan did not contain eligibility requirements more restrictive than, or in addition to, those required under Title IV-A.

(b) The agency may cover any AFDC optional group without covering all such groups.

[46 FR 47985, Sept. 30, 1981]

OPTIONS FOR COVERAGE OF THE AGED, BLIND, AND DISABLED

§ 435.230 Individuals receiving only optional State supplements.

(a) The agency may provide Medicaid, in one or more of the following classifications, to individuals who receive only an optional State supplement that meets the conditions specified in paragraph (b) of this section and who would be eligible for SSI except for the level of their income:

(1) All aged individuals.

(2) All blind individuals.

(3) All disabled individuals.

(4) Only aged individuals in domiciliary facilities or other group living arrangements as defined under SSI.

(5) Only blind individuals in domiciliary facilities or other group living arrangements as defined under SSI.

(6) Only disabled individuals in domiciliary facilities or other group living arrangements as defined under SSI.

(7) Individuals receiving a federally administered optional State supplement that meets the conditions specified in this section.

(8) Individuals in additional classifications specified by the Secretary for federally administered supplementary payments under 20 CFR 416.2020(d).

(b) Payments under the optional supplement program must be—

(1) Based on need and paid in cash on a regular basis;

(2) Equal to the difference between the individual's countable income and the income standard used to determine eligibility for supplement. Countable income is income remaining after deductions required under SSI or, at State option, more liberal deductions are made (see § 435.1006 for limitations on FFP in Medicaid expenditures for individuals receiving optional State supplements); and

(3) Available to all individuals in the State; however, the plan may provide for variations in the income standard by political subdivision according to cost-of-living differences.

§ 435.231 Individuals in institutions who are eligible under a special income level.

(a) If the agency provides Medicaid under § 435.211 to individuals in institutions who would be eligible for AFDC, SSI, or State supplements except for their institutional status, it may also cover aged, blind, and disabled individuals in institutions who—

(1) Because of their income, would not be eligible for SSI or State supplements if they were not institutionalized; but

(2) Have income below a level specified in the plan under § 435.722. (See § 435.1005 for limitations on FFP in Medicaid expenditures for individuals specified in this section.)

(b) The agency may cover individuals under this section whether or not the State pays optional supplements.

[43 FR 45204, Sept. 29, 1978, as amended at 45 FR 24884, Apr. 11, 1980]

Subpart D—Optional Coverage of the Medically Needy

§ 435.300 Scope.

This subpart specifies the option for coverage of medically needy individuals.

§ 435.301 General rules.

(a) A medicaid agency may provide Medicaid to individuals specified in this subpart who—

(1) Either—

(i) Have income that meets the applicable standards in §§ 435.812 through 435.814; or

(ii) If their income is more than allowed under those standards, have incurred medical expenses at least equal to the difference between their income and the applicable income standard; and

(2) Have resources that meet the applicable standards in §§ 435.840 through 435.843.

(b) If the agency chooses this option, the following provisions apply:

(1) The agency must provide Medicaid to the following individuals who meet the requirements of paragraph (a) of this section:

(i) All pregnant women during the course of their pregnancy who, except for income and resources, would be eligible for Medicaid as mandatory or optional categorically needy under subparts B or C of this part;

(ii) All individuals under 18 years of age who, except for income and resources, would be eligible for Medicaid as mandatory categorically needy under subpart B of this part;

(iii) All newborn children born on or after October 1, 1984, to a woman who is eligible as medically needy and is receiving Medicaid on the date of the child's birth. The child is deemed to have applied and been found eligible for Medicaid on the date of birth and remains eligible as medically needy for one year so long as the woman remains eligible and the child is a member of the woman's household. If the woman's basis of eligibility changes to categorically needy, the child is eligible as categorically needy under § 435.117. The woman is considered to remain eligible if she meets the spend-down requirements in any consecutive budget period following the birth of the child.

(2) The agency may provide Medicaid to any of the following groups of individuals;

(i) Individuals under age 21 (§ 435.308).

(ii) Caretaker relatives (§ 435.310).

(iii) Aged (§ 435.330.320 and 435.330).

(iv) Blind (§§ 435.322, 435.330 and 435.340).

(v) Disabled (§§ 435.324, 435.330, and 435.340).

(3) If the agency provides Medicaid to any individual in a group specified in paragraph (b)(2) of this section, the agency must provide Medicaid to all individuals eligible to be members of that group.

[46 FR 47986, Sept. 30, 1981, as amended at 52 FR 43072, Nov. 9, 1987; 52 FR 48438, Dec. 22, 1987]

§ 435.308 Medically needy coverage of individuals under age 21.

(a) If the agency provides Medicaid to the medically needy, it must provide Medicaid to individuals under age 21 (or, at State option, under age 20, 19, or 18), as specified in paragraph (b) of this section, who meet the income and resource standards in Subpart I of this part. (See § 435.301 for required coverage as either categorically or medically needy.)

(b) The agency may cover all individuals described in paragraph (a) of this section or reasonable classifications of those individuals. Examples of reasonable classifications are as follows:

(1) Individuals in foster homes or private institutions for whom a public agency is assuming a full or partial financial responsibility. If the agency covers these individuals, it may also provide Medicaid to individuals placed in foster homes or private institutions by private nonprofit agencies.

(2) Individuals in adoptions subsidized in full or in part by a public agency.

(3) Individuals in intermediate care facilities, if intermediate care facility services are provided under the plan. If the agency covers these individuals, it may also provide Medicaid to individuals in intermediate care facilities for the mentally retarded.

(4) Individuals receiving active treatment as inpatients in psychiatric facilities or programs, if inpatient psychiatric services for individuals under 21 are provided under the plan.

[46 FR 47986, Sept. 30, 1981]

§ 435.310 Medically needy coverage of caretaker relatives.

(a) If the agency provides for the medically needy, it may provide Medicaid to caretaker relatives, as specified in paragraph (b) of this section, who meet the income and resource standards of Subpart I of this part.

(b) "Caretaker relatives" mean individuals who—

(1) Meet the definition of a caretaker relative under 45 CFR 233.90(c)(1)(v)(A); and

(2) Have in their care an individual who is determined to be dependent, as specified in § 435.510.

[46 FR 47986, Sept. 30, 1981]

§ 435.320 Medically needy coverage of the aged in States that cover individuals receiving SSI.

If the agency provides Medicaid to individuals receiving SSI and elects to cover the medically needy, it may provide Medicaid to individuals who—

(a) Are 65 years of age and older, as specified in § 435.520; and

(b) Meet the income and resource requirements of Subpart I of this part.

[46 FR 47986, Sept. 30, 1981]

§ 435.322 Medically needy coverage of the blind in States that cover individuals receiving SSI.

If the agency provides Medicaid to individuals receiving SSI and elects to cover the medically needy, it may provide Medicaid to blind individuals who meet—

(a) The requirements for blindness, as specified in §§ 435.530 and 435.531; and

(b) The income and resource requirements of Subpart I of this part.

[46 FR 47986, Sept. 30, 1981]

§ 435.324 Medically needy coverage of the disabled in States that cover individuals receiving SSI.

If the agency provides Medicaid to individuals receiving SSI and elects to cover the medically needy, it may provide Medicaid to disabled individuals who meet—

(a) The requirements for disability, as specified in §§ 435.540 and 435.541; and

(b) The income and resource requirements of Subpart I of this part.

[46 FR 47986, Sept. 30, 1981; 46 FR 54743, Nov. 11, 1981]

§ 435.326 Individuals who would be ineligible if they were not enrolled in an HMO.

If the agency provides Medicaid to the categorically needy under § 435.212, it may provide Medicaid under the same rules to medically needy recipients who are enrolled in a federally qualified HMO.

[48 FR 54025, Nov. 30, 1983]

§ 435.330 Medically needy coverage of the aged, blind, and disabled in States that impose eligibility requirements more restrictive than used under SSI.

(a) If an agency provides Medicaid as categorically needy only to those aged, blind, or disabled individuals who meet more restrictive requirements than used under SSI and elects to cover the medically needy, it may provide Medicaid as medically needy to those aged, blind, or disabled individuals who—

(1) Are not categorically needy, as specified in paragraph (b) of this section;

(2) Have income and resources within the standards established under Subpart I of this part; and

(3) If applying as blind or disabled, meet the blindness or disability requirements established under § 435.121.

(b) To determine whether an individual is covered as categorically needy or medically needy, the agency must—

(1) Consider as categorically needy those individuals who meet the State's categorically needy financial standard and—

(i) Who, before their incurred medical expenses are deducted from income, meet the financial eligibility requirements for SSI or a State supplement; or

(ii) Whose OASDI increases are not counted under §§ 435.134 and 435.135.

(2) Consider as medically needy all other individuals.

[46 FR 47986, Sept. 30, 1981]

§ 435.340 Protected medically needy coverage for blind and disabled individuals eligible in December 1973.

If an agency provides Medicaid to the medically needy, it must cover individuals who—

(a) Where eligible as medically needy under the Medicaid plan in December 1973 on the basis of the blindness or disability criteria of the AB, APTD, or AABD plan;

(b) For each consecutive month after December 1973, continue to meet—

(1) Those blindness or disability criteria; and

(2) The eligibility requirements for the medically needy under the December 1973 Medicaid plan; and

(c) Meet the current requirements for eligibility as medically needy under the Medicaid plan except for blindness or disability criteria.

[46 FR 47987, Sept. 30, 1981]

Subpart E—General Eligibility Requirements

§ 435.400 Scope.

This subpart prescribes general requirements for determining the eligibility of both categorically and medically needy individuals specified in Subparts B, C, and D of this part.

§ 435.401 General rules.

(a) A Medicaid agency may not impose any eligibility requirement that is prohibited under Title XIX of the Act.

(b) The agency must base any optional group covered under Subparts B and C of this part on reasonable classifications that do not result in arbitrary or inequitable treatment of individuals and groups and that are consistent with the objectives of Title XIX.

(c) The agency must not use requirements for determining eligibility for optional coverage groups that are—

(1) For families and children, more restrictive than those used under the State's AFDC plan; and

(2) For aged, blind, and disabled individuals, more restrictive than those used under SSI, except for individuals

receiving an optional State supplement as specified in § 435.230 or individuals in categories specified by the agency under § 435.121.

§ 435.402 Citizenship and alienage.

The agency must provide Medicaid to otherwise eligible residents of the United States who are—

(a) Citizens; or

(b) Aliens lawfully admitted for permanent residence or permanently residing in the United States under color of law, including any alien who is lawfully present in the United States under section 203(a)(7) or section 212(d)(5) of the Immigration and Nationality Act.

§ 435.403 State residence.

(a) *Requirement.* The agency must provide Medicaid to eligible residents of the State, including residents who are absent from the State. The conditions under which payment for services is provided to out-of-State residents are set forth in § 431.52 of this chapter.

(b) *Definition.* For purposes of this section—"Institution" has the same meaning as "Institution" and "Medical institution", as defined in § 435.1009 of this chapter. For purposes of State placement, the term also includes "foster care homes", licensed as set forth in 45 CFR 1355.20, and providing food, shelter and supportive services to one or more persons unrelated to the proprietor.

(c) *Incapability of indicating intent.* For purposes of this section, an individual is considered incapable of indicating intent if the individual—

(1) Has an I.Q. of 49 or less or has a mental age of 7 or less, based on tests acceptable to the mental retardation agency in the State:

(2) Is judged legally incompetent; or

(3) Is found incapable of indicating intent based on medical documentation obtained from a physician, psychologist, or other person licensed by the State in the field of mental retardation.

(d) *Who is a State resident.* A resident of a State is any individual who:

(1) Meets the conditions in paragraphs (e) through (i) of this section; or

(2) Meets the criteria specified in an interstate agreement under paragraph (k) of this section.

(e) *Placement by a State in an out-of-State institution*—(1) *General rule.* Any agency of the State, including an entity recognized under State law as being under contract with the State for such purposes, that arranges for an individual to be placed in an institution located in another State, is recognized as acting on behalf of the State in making a placement. The State arranging or actually making the placement is considered as the individual's State of residence.

(2) Any action beyond providing information to the individual and the individual's family would constitute arranging or making a State placement. However, the following actions do not constitute State placement:

(i) Providing basic information to individuals about another State's Medicaid program, and information about the availability of health care services and facilities in another State.

(ii) Assisting an individual in locating an institution in another State, provided the individual is capable of indicating intent and independently decides to move.

(3) When a competent individual leaves the facility in which the individual is placed by a State, that individual's State of residence for Medicaid purposes is the State where the individual is physically located.

(4) Where a placement is initiated by a State because the State lacks a sufficient number of appropriate facilities to provide services to its residents, the State making the placement is the individual's State of residence for Medicaid purposes.

(f) *Individuals receiving a State supplementary payment (SSP).* For individuals of any age who are receiving an SSP, the State of residence is the State paying the SSP.

(g) *Individuals receiving Title IV-E payments.* For individuals of any age who are receiving Federal payments for foster care and adoption assistance under title IV-E of the Social Security Act, the State of residence is the State making the payment.

(h) *Individuals under Age 21.* (1) For any individual who is emancipated from his or her parents or who is married and capable of indicating intent, the State of residence is the State where the individual is living with the intention to remain there permanently or for an indefinite period.

(2) For any individual not residing in an institution as defined in paragraph (b) whose Medicaid eligibility is based on blindness or disability, the State of residence is the State in which the individual is living.

(3) For any other non-institutionalized individual not subject to paragraph (h)(1) or (h)(2) of this section, the State of residence is determined in accordance with 45 CFR 233.40, the rules governing residence under the AFDC program.

(4) For any institutionalized individual who is neither married nor emancipated, the State of residence is—

(i) The parent's or legal guardian's State of residence at the time of placement (if a legal guardian has been appointed and parental rights are terminated, the State of residence of the guardian is used instead of the parent's); or

(ii) The current State of residence of the parent or legal guardian who files the application if the individual is institutionalized in that State (if a legal guardian has been appointed and parental rights are terminated, the State or residence of the guardian is used instead of the parent's).

(iii) The State of residence of the individual or party who files an application is used if the individual has been abandoned by his or her parent(s), does not have a legal guardian and is institutionalized in that State.

(i) *Individuals Age 21 and over.* (1) For any individual not residing in an institution as defined in paragraph (b), the State of residence is the State where the individual is—

(i) Living with the intention to remain there permanently or for an indefinite period (or if incapable of stating intent, where the individual is living); or

(ii) Living and which the individual entered with a job commitment or seeking employment (whether or not currently employed).

(2) For any institutionalized individual who became incapable of indicating intent before age 21, the State of residence is—

(i) That of the parent applying for Medicaid on the individual's behalf, if the parents reside in separate States (if a legal guardian has been appointed and parental rights are terminated, the State of residence of the guardian is used instead of the parent's);

(ii) The parent's or legal guardian's State of residence at the time of placement (if a legal guardian has been appointed and parental rights are terminated, the State of residence of the guardian is used instead of the parent's); or

(iii) The current State of residence of the parent or legal guardian who files the application if the individual is institutionalized in that State (if a legal guardian has been appointed and parental rights are terminated, the State of residence of the guardian is used instead of the parent's).

(iv) The State of residence of the individual or party who files an application is used if the individual has been abandoned by his or her parent(s), does not have a legal guardian and is institutionalized in that State.

(3) For any institutionalized individual who became incapable of indicating intent at or after age 21, the State of residence is the State in which the individual is physically present, except where another State makes a placement.

(4) For any other institutionalized individual, the State of residence is the State where the individual is living with the intention to remain there permanently or for an indefinite period.

(j) *Specific prohibitions.* (1) The agency may not deny Medicaid eligibility because an individual has not resided in the State for a specified period.

(2) The agency may not deny Medicaid eligibility to an individual in an institution, who satisfies the residency rules set forth in this section, on the grounds that the individual did not establish residence in the State before entering the institution.

(3) The agency may not deny or terminate a resident's Medicaid eligibility because of that person's temporary absence from the State if the person in-

tends to return when the purpose of the absence has been accomplished, unless another State has determined that the person is a resident there for purposes of Medicaid.

(k) *Interstate agreements.* A State may have a written agreement with another State setting forth rules and procedures resolving cases of disputed residency. These agreements may establish criteria other than those specified in paragraphs (c) through (i) of this section, but must not include criteria that result in loss of residency in both States or that are prohibited by paragraph (j) of this section. The agreements must contain a procedure for providing Medicaid to individuals pending resolution of the case. States may use interstate agreeements for purposes other than cases of disputed residency to facilitate administration of the program, and to facilitate the placement and adoption of title IV-E individuals when the child and his or her adoptive parent(s) move into another State.

(l) *Continued Medicaid for institutionalized recipients.* If an agency is providing Medicaid to an institutionalized recipient who, as a result of this section, would be considered a resident of a different State—

(1) The agency must continue to provide Medicaid to that recipient from June 24, 1983 until July 5, 1984, unless it makes arrangements with another State of residence to provide Medicaid at an earlier date: and

(2) Those arrangements must not include provisions prohibited by paragraph (h) of this section.

(m) *Cases of disputed residency.* Where two or more States cannot resolve which State is the State of residence, the State where the individual is physically located is the State of residence.

[49 FR 13531, Apr. 5, 1984]

§ 435.404 Applicant's choice of category.

The agency must allow an individual who would be eligible under more than one category to have his eligibility determined for the category he selects.

Subpart F—Categorical Requirements for Eligibility

§ 435.500 Scope.

This subpart prescribes categorical requirements for determining the eligibility of both categorically and medically needy individuals specified in Subparts B, C, and D of this part.

DEPENDENCY

§ 435.510 Determination of dependency.

For families with dependent children who are not receiving AFDC, the agency must use the definitions and procedures set forth under the State's AFDC plan to determine whether—

(a) An individual under age 21 is a dependent child because he is deprived of parental support or care; and

(b) An individual is an eligible member of a family with dependent children.

AGE

§ 435.520 Age requirements for the aged and children.

(a) The agency must not impose—

(1) An age requirement of more than 65 years;

(2) An age requirement that excludes an individual under age 19 who meets the definition of dependent child under the State title IV-A plan; or

(3) A lower age requirement than that under the State's AFDC plan.

(b) In determining age, the agency must use the common-law method (under which an age is reached the day before the anniversary of birth), except—

(1) For families and children, the agency must use the popular usage method (under which an age is reached on the anniversary of birth), if this method is used under the State's AFDC plan; and

(2) For aged, blind, or disabled individuals, the agency may use the popular usage method, if the plan provides under § 435.121, for coverage of aged, blind, or disabled individuals who meet more restrictive eligibility requirements than those under SSI.

(c) The agency may use an arbitrary date, such as July 1, for determining an individual's age if the year, but not the month, of his birth is known.

[43 FR 45204, Sept. 29, 1978, as amended at 46 FR 47987, Sept. 30, 1981]

BLINDNESS

§ 435.530 Definition of blindness.

(a) *Definition.* The agency must use the same definition of blindness as used under SSI, except that—

(1) In determining the eligibility of individuals whose Medicaid eligibility is protected under §§ 435.130 through 435.134, the agency must use the definition of blindness that was used under the Medicaid plan in December 1973; and

(2) The agency may use a more restrictive definition to determine eligibility under § 435.121, if the definition is no more restrictive than that used under the Medicaid plan on January 1, 1972.

(b) *State plan requirement.* The State plan must contain the definition of blindness, expressed in ophthalmic measurements.

§ 435.531 Determinations of blindness.

(a) Except as specified in paragraph (b) of this section, in determining blindness—

(1) A physician skilled in the diseases of the eye or an optometrist, whichever the individual selects, must examine him, unless both of the applicant's eyes are missing;

(2) The examiner must submit a report of examination to the Medicaid agency; and

(3) A physician skilled in the diseases of the eye (for example, an ophthalmologist or an eye, ear, nose, and throat specialist) must review the report and determine on behalf of the agency—

(i) Whether the individual meets the definition of blindness; and

(ii) Whether and when re-examinations are necessary for periodic redeterminations of eligibility, as required under § 435.916 of this part.

(b) If an agency provides Medicaid to individuals receiving SSI on the basis of blindness, this section does not apply for those individuals.

[43 FR 45204, Sept. 29, 1978, as amended at 44 FR 17937, Mar. 23, 1979]

DISABILITY

§ 435.540 Definition of disability.

(a) *Definition.* The agency must use the same definition of disability as used under SSI, except that—

(1) In determining the eligibility of individuals whose Medicaid eligibility is protected under §§ 435.130 through 435.134, the agency must use the definition of disability that was used under the Medicaid plan in December 1973; and

(2) The agency may use a more restrictive definition to determine eligibility under § 435.121, if the definition is no more restrictive than that used under the Medicaid plan on January 1, 1972.

(b) *State plan requirements.* The State plan must contain the definition of disability.

§ 435.541 Determinations of disability.

(a) Except as specified in paragraph (d) of this section, the agency must obtain a medical report and a social history for individuals applying for Medicaid on the basis of disability. The medical report must include a diagnosis based on medical evidence. The social history must contain enough information to enable the agency to determine disability.

(b) A physician and a social worker, qualified by professional training and experience, must review the medical report and social history and determine on behalf of the agency whether the individual meets the definition of disability. The physician must determine whether and when reexaminations will be necessary for periodic redeterminations of eligibility as required under § 435.916 of this part.

(c) In subsequently determining disability, the physician and social worker must review reexamination reports and the social history and determine whether the individual continues to meet the definition.

(d) If an agency provides Medicaid to individuals receiving SSI on the basis of disability, this section does not apply for those individuals.

[43 FR 45204, Sept. 29, 1978, as amended at 44 FR 17937, Mar. 23, 1979]

Subpart G—General Financial Eligibility Requirements and Options

§ 435.600 Scope.

This subpart prescribes general financial requirements and options for determining the eligibility of both categorically and medically needy individuals specified in Subparts B, C, and D of this part. Subparts H and I prescribe additional financial requirements.

[43 FR 45204, Sept. 29, 1978, as amended at 45 FR 8986, Feb. 11, 1980]

§ 435.602 Limitation on the financial responsibility of relatives.

(a) Except for a spouse of an individual or a parent for a child who is under age 21 or blind or disabled, the agency must not—

(1) Consider income and resources of any relative available to an individual; nor

(2) Collect reimbursement from any relative for amounts paid by the agency for services provided to an individual.

(b) The income and resources of spouses and parents must be considered in determining financial eligibility as provided for the categorically needy in Subpart H and the medically needy in Subpart I of this part.

[45 FR 82258, Dec. 15, 1980]

§ 435.603 Applications for other benefits.

(a) As a condition of eligibility, the agency must require applicants and recipients to take all necessary steps to obtain any annuities, pensions, retirement, and disability benefits to which they are entitled, unless they can show good cause for not doing so.

(b) Annuities, pensions, retirement and disability benefits include, but are not limited to, veterans' compensation and pensions, OASDI benefits, railroad retirement benefits, and unemployment compensation.

§ 435.604 Assignment of rights to benefits.

For medical assistance furnished on or after October 1, 1984—

(a) As a condition of eligibility, the agency must require legally able applicants and recipients to assign rights to medical support or other third party payments to the Medicaid agency and to cooperate with the agency in obtaining medical support or payments. (Part 433, Subpart D, contains specific requirements for these assignments.)

(b) The requirements for assignment of rights must be applied uniformly for all groups covered under the plan.

[50 FR 46666, Nov. 12, 1985]

Subpart H—Financial Requirements for the Categorically Needy

§ 435.700 Scope.

This subpart prescribes financial requirements for determining the eligibility of categorically needy individuals under Subparts B and C of this part. The requirements apply only to individuals who are not receiving AFDC, SSI, or an optional State supplement. The financial eligibility requirements of AFDC, SSI, or the State supplement apply to individuals receiving those payments. This subpart also prescribes requirements for applying an institutionalized recipient's income to cost of care.

Financial Requirements Applicable to Optional Groups: Families and Children

§ 435.711 General requirements.

In determining eligibility for families and children, a Medicaid agency must apply the financial eligibility requirements of the State's AFDC plan.

§ 435.712 Financial responsibility of spouses and parents.

(a) For families and children, the agency must consider income and resources of spouses or parents as available to the individual whether or not they are actually contributed, if they live in the same household. For this purpose, "parent" includes a stepparent if he is equally liable with the natural parent for the support of children under State law of general applicability.

(b) If the spouse or parent does not live with the individual, the agency must consider only income and resources that are actually contributed to the individual from a parent or spouse as available to him.

(c) Even if State law confers adult status below age 21, the agency must consider parental income and resources as available to a child, if he is living with the parent, until he becomes 21.

FINANCIAL ELIGIBILITY REQUIREMENTS APPLICABLE TO OPTIONAL GROUPS: THE AGED, BLIND, AND DISABLED IN STATES COVERING INDIVIDUALS RECEIVING SSI

§ 435.721 General requirements.

(a) This section applies when an agency provides Medicaid to—

(1) All SSI recipients or to all SSI recipients and to State supplement recipients; and

(2) One or more of the optional coverage groups specified in §§ 435.210 (eligible for but not receiving cash), 435.211 and 435.231 (institutionalized individuals).

(b) If the agency, under § 435.120, provides Medicaid to SSI recipients but not to optional State supplement recipients, it must use the SSI financial eligibility requirements to determine Medicaid eligibility of aged, blind, and disabled individuals under the optional provisions of §§ 435.210, 435.211, and 435.231. However, under § 435.231, it may use a higher income standard than SSI to determine eligibility for institutionalized individuals.

(c) If the agency provides Medicaid to SSI recipients and, under § 435.230, to individuals who are not receiving SSI but are receiving optional State supplements, the agency must use the following criteria to determine Medicaid eligibility under the optional provisions of §§ 435.210, 435.211, and 435.231 for aged, blind, and disabled individuals:

(1) The agency must use the SSI financial eligibility requirements for individuals who would be eligible for SSI but would not be eligible for an optional State supplement.

(2) The agency must use the supplement program's financial eligibility requirements for individuals who would be eligible for an optional State supplement. However, the agency may use a higher income standard than SSI or the State supplement program to determine eligibility of institutionalized individuals under § 435.231.

(d) In determining eligibility under paragraph (b) or (c) of this section, the agency must use the SSI deductions from income and resources and budgeting methods set forth in 20 CFR Part 416, unless greater deductions from income and higher income standards are used in an optional State supplement program that meets the requirements of § 435.230.

§ 435.722 Individuals in institutions who are eligible under a special income level.

(a) If an agency, under § 435.231, provides Medicaid to individuals in medical institutions and intermediate care facilities who would not be eligible for SSI or State supplements if they were not institutionalized, the agency must use income standards based on the greater need for financial assistance that the individuals would have if they were not in the institution. The standards may vary by the level of institutional care needed by the individual (hospital, skilled nursing, or intermediate level care), or by other factors related to individual needs. (See § 435.1005 for FFP limits on income standards established under this section.)

(b) In determining the eligibility of individuals under the income standards established under this section, the agency must not take into account income that would be disregarded in determining eligibility for SSI or for an optional State supplement.

(c) The agency must apply the income standards established under this section effective with the first day of a period of not less than 30 consecutive days of institutionalization.

[43 FR 45204, Sept. 29, 1978, as amended at 45 FR 24884, Apr. 11, 1980; 53 FR 3595, Feb. 8, 1988]

§ 435.723 Financial responsibility of spouses.

(a) If the agency provides Medicaid to SSI recipients, it must meet the requirements of this section in determining eligibility of aged, blind, and disabled individuals under the optional coverage provisions of §§ 435.210, 435.211, and 435.231.

(b) The agency must consider income and resources of spouses living in the same household as available to each other, whether or not they are actually contributed.

(c) If both spouses apply or are eligible as aged, blind, or disabled and cease to live together, the agency must consider their income and resources as available to each other for the time periods specified below. After the appropriate time period, the agency must consider only the income and resources that are actually contributed by one spouse to the other.

(1) If spouses cease to live together because of the institutionalization of one spouse—

(i) The agency must consider their income as available to each other through the month in which they cease to live together. Mutual consideration of income ceases with the month after the month in which separation occurs.

(ii) The agency must consider their resources as available to each other for the month during which they cease to live together and the six months following that month.

(2) If spouses cease to live together for any reason other than institutionalization, the agency must consider their income and resources as available to each other for the month during which they cease to live together and the six months following that month. If the mutual consideration of income and resources causes the individuals to lose eligibility as a couple, the agency will determine if an individual is eligible in accordance with paragraph (d) of this section.

(d) If only one spouse in a couple applies or is eligible, or both spouses apply and are not eligible as a couple, and they cease to live together, the agency must consider only the income and resources of the ineligible spouse that are actually contributed to the eligible spouse beginning with the month after the month in which they cease to live together.

[43 FR 45204, Sept. 29, 1978, as amended at 48 FR 39629, Sept. 1, 1983]

§ 435.724 Financial responsibility of parents for blind or disabled children.

(a) If the agency provides Medicaid to SSI recipients, it must meet the requirements of this section in determining eligibility of blind and disabled children under the optional coverage provisions of §§ 435.210, 435.211, and 435.231.

(b) If the child is under age 18 and is living in the same household with a parent or spouse of a parent, the agency must consider the parent's or spouse's income and resources available to the child, whether or not they are actually contributed. This rule also applies to a child under 21 living in the same household, if he is regularly attending a school, college, or university or is receiving technical training designed to prepare him for gainful employment.

(c) After the month in which the child ceases to live with a parent or spouse of a parent, the agency must consider only the income and resources of that parent or spouse that are actually contributed to the child. This rule applies even if the child returns to the household for periodic visits.

[43 FR 45204, Sept. 29, 1978, as amended at 44 FR 17937, Mar. 23, 1979]

§ 435.725 Post-eligibility treatment of income and resources of institutionalized individuals: Application of patient income to the cost of care.

(a) *Application of patient income.* The agency must reduce its payment to an institution, for services provided to an individual specified in paragraph (b) of this section, by the amount that remains after deducting the amounts specified in paragraphs (c) and (d) of this section, from the individual's total income, as determined in paragraph (e) of this section.

(b) *Applicability.* This section applies to the following individuals in medical institutions and intermediate care facilities.

(1) Individuals receiving cash assistance under SSI or AFDC who are eligible for Medicaid under § 435.110 or § 435.120.

(2) Individuals who would be eligible for AFDC, SSI, or an optional State

supplement except for their institutional status and who are eligible for Medicaid under § 435.211.

(3) Aged, blind, and disabled individuals who are eligible for Medicaid, under § 435.231, under a higher income standard than the standard used in determining eligibility for SSI or optional State supplements.

(c) *Required deductions.* In reducing its payment to the institution, the agency must deduct the following amounts, in the following order, from the individual's total income, as determined under paragraph (e) of this section. Income that was disregarded in determining eligibility must be considered in this process.

(1) A personal needs allowance that is reasonable in amount for clothing and other personal needs of the individual while in the institution. This protected personal needs allowance must be at least—

(i) $25 a month for an aged, blind, or disabled individual, including a child applying for Medicaid on the basis of blindness or disability;

(ii) $50 a month for an institutionalized couple if both spouses are aged, blind, or disabled and their income is considered available to each other in determining eligibility; and

(iii) For other individuals, a reasonable amount set by the agency, based on a reasonable difference in their personal needs from those of the aged, blind, and disabled.

(2) For an individual with only a spouse at home, an additional amount for the maintenance needs of the spouse. This amount must be based on a reasonable assessment of need but must not exceed the highest of—

(i) The amount of the income standard used to determine eligibility for SSI for an individual living in his own home, if the agency provides Medicaid only to individuals receiving SSI;

(ii) The amount of the highest income standard, in the appropriate category of age, blindness, or disability, used to determine eligibility for an optional State supplement for an individual in his own home, if the agency provides Medicaid to optional State supplement recipients under § 435.230; or

(iii) The amount of the medically needy income standard for one person established under § 435.812, if the agency provides Medicaid under the medically needy coverage option.

(3) For an individual with a family at home, an additional amount for the maintenance needs of the family. This amount must—

(i) Be based on a reasonable assessment of their financial need;

(ii) Be adjusted for the number of family members living in the home; and

(iii) Not exceed the higher of the need standard for a family of the same size used to determine eligibility under the State's AFDC plan or the medically needy income standard established under Subpart I of this part for a family of the same size.

(4) Amounts for Medicare and other health insurance premiums, deductibles, or coinsurance charges that are not subject to payment by a third party.

(d) *Optional deductions.* In determining the amount of the individual's income to be used to reduce the agency's payment to the institution, the agency may deduct the following amounts from the individual's total income as determined under paragraph (e) of this section:

(1) Necessary medical or remedial services included in the State's Medicaid plan for the categorically needy, which exceed limitations on amount, duration or scope imposed by the agency, subject to reasonable limits the agency may establish on amounts of these expenses;

(2) Necessary medical or remedial care recognized under State law but not covered under the State's Medicaid plan, subject to reasonable limits the agency may establish on amounts of these expenses; and

(3) For single individuals and couples, an amount (in addition to the personal needs allowance) for maintenance of the individual's or couple's home if—

(i) The amount is deducted for not more than a 6-month period; and

(ii) A physician has certified that either of the individuals is likely to return to the home within that period.

(e) *Determination of income*—(1) *Option.* In determining the amount of an individual's income to be used to reduce the agency's payment to the institution, the agency may use total income received, or it may project monthly income for a prospective period not to exceed 6 months.

(2) *Basis for projection.* The agency must base the projection on income received in the preceding period, not to exceed 6 months, and on income expected to be received.

(3) *Adjustments.* At the end of the prospective period specified in paragraph (e)(1) of this section, or when any significant change occurs, the agency must reconcile estimates with income received.

(f) *Determination of medical expenses*—(1) *Option.* In determining the amount of medical expenses to be deducted from an individual's income, the agency may deduct incurred medical expenses, or it may project medical expenses for a prospective period not to exceed 6 months.

(2) *Basis for projection.* The agency must base the estimate on medical expenses incurred in the preceding period, not to exceed 6 months, and on medical expenses expected to be incurred.

(3) *Adjustments.* At the end of the prospective period specified in paragraph (f)(1) of this section, or when any significant change occurs, the agency must reconcile estimates with incurred medical expenses.

[43 FR 45204, Sept. 29, 1978, as amended at 45 FR 24884, Apr. 11, 1980; 48 FR 5735, Feb. 8, 1983; 53 FR 3595, Feb. 8, 1988]

§ 435.726 Post-eligibility treatment of income and resources of individuals receiving home and community-based services furnished under a waiver: Application of patient income to the cost of care.

(a) The agency must reduce its payment for home and community-based services provided to an individual specified in paragraph (b) of this section, by the amount that remains after deducting the amounts specified in paragraph (c) of this section from the individual's income.

(b) This section applies to individuals who are eligible for Medicaid under § 435.217 and are receiving home and community-based services furnished under a waiver of Medicaid requirements under Part 441, Subpart G of this subchapter.

(c) In reducing its payment for home and community-based services, the agency must deduct the following amounts, in the following order, from the individual's total income (including amounts disregarded in determining eligibility):

(1) An amount for the maintenance needs of the individual. This amount must be based on a reasonable assessment of need but must not exceed the highest of—

(i) The amount of the income standard used to determine eligibility for SSI for an individual living in his own home, if the agency provides Medicaid only to individuals receiving SSI;

(ii) The amount of the highest income standard, in the appropriate category of age, blindness, or disability, used to determine eligibility for an optional State supplement for an individual in his own home, if the agency provides Medicaid to optional State supplement recipients under § 435.230; or

(iii) The amount of the medically needy income standard for one person established under §§ 435.811 and 435.814, if the agency provides Medicaid under the medically needy coverage option.

(2) For an individual with only a spouse at home, an additional amount for the maintenance needs of the spouse. This amount must be based on a reasonable assessment of need but must not exceed the highest of—

(i) The amount of the income standard used to determine eligibility for SSI for an individual living in his own home, if the agency provides Medicaid only to individuals receiving SSI;

(ii) The amount of the highest income standard, in the appropriate category of age, blindness, or disability, used to determine eligibility for an optional State supplement for an individual in his own home, if the agency provides Medicaid to optional State supplement recipients under § 435.230; or

(iii) The amount of the medically needy income standard for one person established under §§ 435.811 and 435.814, if the agency provides Medicaid under the medically needy coverage option.

(3) For an individual with a family at home, an additional amount for the maintenance needs of the family. This amount must—

(i) Be based on a reasonable assessment of their financial need;

(ii) Be adjusted for the number of family members living in the home; and

(iii) Not exceed the higher of the need standard for a family of the same size used to determine eligibility under the State's AFDC plan or the medically needy income standard established under subpart I of this part for a family of the same size.

(4) Amounts for incurred expenses for medical or remedial care that are not subject to payment by a third party including—

(i) Medicare and other health insurance premiums, deductibles, or coinsurance charges; and

(ii) Necessary medical or remedial care recognized under State law but not covered under the State's Medicaid plan, subject to reasonable limits the agency may establish on amounts of these expenses.

[46 FR 48539, Oct. 1, 1981, as amended at 50 FR 10026, Mar. 13, 1985]

FINANCIAL ELIGIBILITY FOR THE AGED, BLIND, AND DISABLED IN STATES USING MORE RESTRICTIVE REQUIREMENTS THAN SSI

§ 435.731 General requirements for determining income eligibility in States using more restrictive requirements than SSI.

Requirements applicable to all individuals. If the agency, under § 435.121, uses any requirement for aged, blind, or disabled individuals more restrictive than an eligibility requirement under SSI, the agency must determine income in accordance with § 435.732 with respect to any category for which more restrictive requirements are imposed. The agency must use the procedures in § 435.732 regardless of the type of restrictive eligibility factor imposed.

[45 FR 24884, Apr. 11, 1980]

§ 435.732 Procedures for determining income eligibility.

The agency must determine income eligibility of individuals in the categories specified in § 435.731 in the following manner:

(a) *Determining countable income.* The agency must deduct the following amounts from income to determine the individual's countable income:

(1) Any SSI benefit the individual receives.

(2) Any optional State supplement the individual receives.

(3) Increases in OASDI that are deducted under §§ 435.134 and 435.135(c) for individuals specified in those sections.

(4) Other deductions from income applied under the Medicaid plan.

(b) *Eligibility based on countable income.* If countable income determined under paragraph (a) of this section is equal to or less than the applicable income standard established under § 435.121 the individual is eligible for Medicaid.

(c) *Deduction of incurred medical expenses.* (1) If countable income exceeds the income standard, the agency must deduct from income expenses incurred by the individual or financially responsible relatives for necessary medical and remedial services that are recognized under State law and are not subject to payment by a third party, including Medicare and other health insurance premiums, deductibles or coinsurance charges, and copayments or deductibles imposed under § 447.51 or § 447.53 of this subchapter.

(2) The agency may set reasonable limits on the amounts of incurred medical expenses to be deducted from income.

(d) *Eligibility based on incurred medical expenses.* If, after incurred medical expenses are deducted, remaining income is equal to or less than the income standard, the individual is eligible for Medicaid.

[45 FR 24884, Apr. 11, 1980]

§ 435.733 Post-eligibility treatment of income and resources of institutionalized individuals: Application of patient income to the cost of care.

(a) *Application of patient income.* The agency must reduce its payment to an institution, for services provided to an individual specified in paragraph (b) of this section, by the amount that remains after deducting the amounts specified in paragraphs (c) and (d) of this section from the individual's total income, as determined in paragraph (e) of this section.

(b) *Applicability.* This section applies to the following individuals in medical institutions and intermediate care facilities:

(1) Individuals receiving cash assistance under AFDC who are eligible for Medicaid under § 435.110 and individuals eligible under § 435.121.

(2) Individuals who would be eligible for AFDC, SSI, or an optional State supplement except for their institutional status and who are eligible for Medicaid under § 435.211.

(3) Aged, blind, and disabled individuals who are eligible for Medicaid, under § 435.231, under a higher income standard than the standard used in determining eligibility for SSI or optional State supplements.

(c) *Required deductions.* The agency must deduct the following amounts, in the following order, from the individual's total income, as determined under paragraph (e) of this section. Income that was disregarded in determining eligibility must be considered in this process.

(1) A personal needs allowance that is reasonable in amount for clothing and other personal needs of the indvidual while in the institution. This protected personal needs allowance must be at least—

(i) $25 a month for an aged, blind, or disabled individual, including a child applying for Medicaid on the basis of blindness or disability;

(ii) $50 a month for an institutionalized couple if both spouses are aged, blind, or disabled and their income is considered available to each other in determining eligibility; and

(iii) For other individuals, a reasonable amount set by the agency, based on a reasonable difference in their personal needs from those of the aged, blind, and disabled.

(2) For an individual with only a spouse at home, an additional amount for the maintenance needs of the spouse. This amount must be based on a reasonable assessment of need but must not exceed the higher of—

(i) The more restrictive income standard established under § 435.121; or

(ii) The medically needy standard for an individual;

(3) For an individual with a family at home, an additional amount for the maintenance needs of the family. This amount must—

(i) Be based on a reasonable assessment of their financial need;

(ii) Be adjusted for the number of family members living in the home; and

(iii) Not exceed the higher of the need standard for a family of the same size used to determine eligibility under the State's AFDC plan or the medically needy income standard established under subpart I of this part for a family of the same size.

(4) Amounts for Medicare and other health insurance premiums, deductibles, or coinsurance charges that are not subject to payment by a third party.

(d) *Optional deductions.* In determining the amount of the individual's income to be used to reduce the agency's payment to the institution, the agency may deduct the following amounts from the individual's total income as determined under paragraph (e) of this section:

(1) Necessary medical or remedial services included in the State's Medicaid plan for the categorically needy, which exceed limitations on amount, duration or scope imposed by the agency, subject to reasonable limits the agency may establish on amounts of these expenses;

(2) Necessary medical or remedial care recognized under State law but not covered under the State's Medicaid plan, subject to reasonable limits the agency may establish on amounts of these expenses; and

(3) For single individuals and couples, an amount (in addition to the personal needs allowance) for mainte-

nance of the individual's or couple's home if—

(i) The amount is deducted for not more than a 6-month period; and

(ii) A physician has certified that either of the individuals is likely to return to the home within that period.

(e) *Determination of income*—(1) *Option.* In determining the amount of an individual's income to be used to reduce the agency's payment to the institution, the agency may use total income received, or it may project total monthly income for a prospective period not to exceed 6 months.

(2) *Basis for projection.* The agency must base the projection on income received in the preceding period, not to exceed 6 months, and on income expected to be received.

(3) *Adjustments.* At the end of the prospective period specified in paragraph (e)(1) of this section, or when any significant change occurs, the agency must reconcile estimates with income received.

(f) *Determination of medical expenses*—(1) *Option.* In determining the amount of medical expenses that may be deducted from an individual's income, the agency may deduct incurred medical expenses, or it may project medical expenses for a prospective period not to exceed 6 months.

(2) *Basis for projection.* The agency must base the estimate on medical expenses incurred in the preceding period, not to exceed 6 months, and medical expenses expected to be incurred.

(3) *Adjustments.* At the end of the prospective period specified in paragraph (f)(1) of this section, or when any significant change occurs, the agency must reconcile estimates with incurred medical expenses.

[45 FR 24884, Apr. 11, 1980, as amended at 48 FR 5735, Feb. 8, 1983; 53 FR 3596, Feb. 8, 1988]

§ 435.734 Financial responsibility of spouses and parents.

(a) In determining Medicaid eligibility of an aged, blind, or disabled individual under requirements more restrictive than those used under SSI, the agency must consider the income and resources of spouses and parents as available to the individual in the manner specified in §§ 435.723 and 435.724 or in a more extensive manner, but not more extensive than the requirements in effect under the Medicaid plan on January 1, 1972.

(b) The agency may consider deemed income and resources of spouses and parents as unavailable to an individual when:

(1) The spouse, or parents (or spouse of a parent) are living in the same household as the individual; and

(2) The Secretary determines under authority in section 1614(f) of the Act, 20 CFR 416.1161a, 426.1204a and notifies the agency that deeming of income and resources under the usual SSI deeming rules is inequitable.

[48 FR 39629, Sept. 1, 1983, as amended at 49 FR 5747, Feb. 15, 1984]

§ 435.735 Post-eligibility treatment of income and resources of individuals receiving home and community-based services furnished under a waiver: Application of patient income to the cost of care.

(a) The agency must reduce its payment for home and community-based services provided to an individual specified in paragraph (b) of this section, by the amount that remains after deducting the amounts specified in paragraph (c) of this section from the individual's income.

(b) This section applies to individuals who are eligible for Medicaid under § 435.217, and are eligible for home and community-based services furnished under a waiver of State plan requirements under Part 441, Subpart G of this subchapter.

(c) In reducing its payment for home and community-based services, the agency must deduct the following amounts, in the following order, from the individual's total income (including amounts disregarded in determining eligibility):

(1) An amount for the maintenance needs of the individual. This amount must be based on a reasonable assessment of need but must not exceed the higher of—

(i) The more restrictive income standard established under § 435.121; or

(ii) The medically needy standard for an individual.

(2) For an individual with only a spouse at home, an additional amount for the maintenance needs of the spouse. This amount must be based on a reasonable assessment of need but must not exceed the higher of—

(i) The more restrictive income standard established under § 435.121; or

(ii) The medically needy standard for an individual.

(3) For an individual with a family at home, an additional amount for the maintenance needs of the family. This amount must—

(i) Be based on a reasonable assessment of their financial need;

(ii) Be adjusted for the number of family members living in the home; and

(iii) Not exceed the higher of the need standard for a family of the same size used to determine eligibility under the State's approved AFDC plan or the medically needy income standard established under Subpart I of this part for a family of the same size.

(4) Amounts for incurred expenses for medical or remedial care that are not subject to payment by a third party, including—

(i) Medicare and other health insurance premiums, deductibles, or coinsurance charges; and

(ii) Necessary medical or remedial care recognized under State law but not covered under the State's Medicaid plan, subject to reasonable limits the agency may establish on amounts of these expenses.

[46 FR 48540, Oct. 1, 1981, as amended at 50 FR 10026, Mar. 13, 1985]

FINANCIAL REQUIREMENTS APPLICABLE TO INDIVIDUALS UNDER PROTECTED COVERAGE PROVISIONS

§ 435.740 Protected Medicaid eligibility for individuals eligible in December 1973.

In determining whether individuals continue to meet the income requirements used in December 1973, for purposes of determining eligibility under §§ 435.131, 435.132, and 435.133, the agency must deduct increased OASDI payments to the same extent that these deductions were in effect in December 1973. These deductions are required by section 306 of the Social Security Amendments of 1972 (Pub. L. 92-603) and section 1007 of Pub. L. 91-172 (enacted Dec. 30, 1969), modified by section 304 of Pub. L. 92-603.

Subpart I—Financial Requirements for the Medically Needy

§ 435.800 Scope.

This subpart prescribes financial requirements for determining the eligibility of medically needy individuals under Subpart D of this part.

MEDICALLY NEEDY INCOME STANDARDS

§ 435.811 Medically needy income standards: General requirements.

To determine eligibility of medically needy individuals, a Medicaid agency must use an income standard under this subpart that is—

(a) Based on family size;

(b) Uniform for all individuals in a covered group;

(c) For FFP purposes, not in excess of 133⅓ percent of the highest money payment that ordinarily would be made in the State AFDC program to an individual or a family of comparable size (see § 435.1007); and

(d) Reasonable (see § 435.812).

[46 FR 47987, Sept. 30, 1981]

§ 435.812 Medically needy income standards: Reasonableness.

(a) The agency must use a medically needy income standard that is reasonable.

(b) The following medically needy income standards are presumed to be reasonable:

(1) The agency provides one medically needy income standard for all covered medically needy groups. Except as provided in paragraphs (c) and (d) of this section, the standard must at least equal the highest income or payment standard used to determine eligibility in the cash assistance programs (or an optional State supplement, if the agency provides Medicaid under § 435.230) related to the covered medically needy groups.

(2) The agency provides a different medically needy income standard for

each covered medically needy group. Except as provided in paragraphs (c) and (d) of this section, the standard for each covered group must at least equal the income or payment standard used to determine eligibility in the cash assistance program (or an optional State supplement, if the agency provides Medicaid under § 435.230) related to that covered medically needy group.

(c) The agency may use a lower medically needy income standard than the standards specified in paragraph (b) of this section if—

(1) The income standard used under paragraph (b) of this section exceeds the maximum dollar amount on income allowed for purposes of FFP under § 435.1007; and

(2) The lower income standard at least equals the maximum amount allowed for purposes of FFP.

(d) In the case of an agency that provides Medicaid for the aged, blind, or disabled individuals only if they meet more restrictive requirements than used under SSI, the following provisions apply:

(1) The agency may use an income standard for those individuals that is lower than the standard specified in paragraph (b) of this section.

(2) The lower standard must at least equal the medically needy income standard for those aged, blind, or disabled individuals under the State's plan on January 1, 1972.

(e) If the agency uses a medically needy income standard not specified in paragraphs (b) through (d) of this section—

(1) That standard is not presumed to be reasonable; and

(2) HCFA must approve the standard.

[46 FR 47987, Sept. 30, 1981]

§ 435.814 Medically needy income standards: State plan requirements.

(a) The State plan must specify the income standard for each covered medically needy group.

(b) If the agency uses an income standard that is not presumed to be reasonable under § 435.812, the State plan must describe that standard.

[46 FR 47987, Sept. 30, 1981]

FINANCIAL RESPONSIBILITY OF RELATIVES

§ 435.821 Financial responsibility of relatives: Individuals under age 21 and caretaker relatives.

(a) The agency must meet the requirements of this section in determining eligibility—

(1) Under § 435.308 of medically needy individuals under age 21; and

(2) Under § 435.310 of medically needy caretaker relatives.

(b) The agency must consider the parent's or spouse's income and resources as available if they are actually contributed to the individual.

(c) The agency may consider income and resources of spouses or parents as available to the individual even if they are not actually contributed to the individual.

[46 FR 47988, Sept. 30, 1981; 46 FR 54743, Nov. 4, 1981]

§ 435.822 Financial responsibility of relatives of aged, blind, or disabled individuals in States using SSI eligibility requirements.

(a) The agency must meet the requirements of this section in determining eligibility—

(1) Under § 435.320 of medically needy aged individuals;

(2) Under § 435.322 of medically needy blind individuals; and

(3) Under § 435.324 of medically needy disabled individuals.

(b) For aged, blind, or disabled individuals with spouses, the agency—

(1) Must consider income and resources as available if they are actually contributed by one spouse to another; and

(2) May consider income and resources of spouses as available to each other even if they are not actually contributed.

(c) For blind or disabled individuals under age 21—

(1) The agency must consider the parent's or spouse's income and resources as available if they are actually contributed to the individual; and

(2) The agency may consider the parent's or spouse's income and resources as available even if they are not actually contributed.

[46 FR 47988, Sept. 30, 1981; 46 FR 54743, Nov. 4, 1981]

§ 435.823 Financial responsibility of relatives of aged, blind, or disabled individuals in States using more restrictive requirements than SSI.

(a) The agency must meet the requirements of this section in determining eligibility under § 435.330 of medically needy aged, blind, and disabled individuals.

(b) For aged, blind, or disabled individuals with spouses, the agency—

(1) Must consider income and resources as available if they are actually contributed by one spouse to the other; and

(2) May consider income and resources of spouses as available to each other even if they are not actually contributed.

(c) For blind or disabled individuals under age 21, the agency—

(1) Must consider the parent's or spouse's income and resources as available if they are actually contributed to the individual; and

(2) May consider the parent's or spouse's income and resources as available even if they are not actually contributed.

[46 FR 47988, Sept. 30, 1981]

MEDICALLY NEEDY INCOME ELIGIBILITY

§ 435.831 Income eligibility.

The agency must determine income eligibility of medically needy individuals in accordance with this section. The agency must use a prospective period of not more than 6 months to compute income.

(a) *Determining countable income.* The agency must deduct the following amounts from income to determine the individual's countable income.

(1) For individuals under age 21 and caretaker relatives, the agency must deduct amounts that would be deducted in determining eligibility under the State's AFDC plan.

(2) For aged, blind, or disabled individuals in States covering all SSI recipients, the agency must deduct amounts that would be deducted in determining eligibility under SSI. However, the agency must also deduct the highest amounts from income that would be deducted in determining eligibility for optional State supplements if these supplements are paid to all individuals who are receiving SSI or would be eligible for SSI except for their income.

(3) For aged, blind, or disabled individuals in States using income requirements more restrictive than SSI, the agency must deduct amounts that are no more restrictive than those used under the Medicaid plan on January 1, 1972 and no more liberal than those deducted in determining eligibility under SSI or an optional State supplement. However, the amounts must be at least the same as those that would be deducted in determining eligibility, under § 435.121, of the categorically needy.

(b) *Eligibility based on countable income.* If countable income determined under paragraph (a) of this section is equal to or less than the applicable income standard under § 435.814, the individual or family is eligible for Medicaid.

(c) *Deduction of incurred medical expenses.* (1) If countable income exceeds the income standard, the agency must deduct from income, in the following order, incurred medical expenses that are not subject to payment by a third party:

(i) Medicare and other health insurance premiums, deductibles, or coinsurance charges, incurred by the individual or family or financially responsible relatives, including enrollment fees, copayments, or deductibles imposed under § 447.51 or § 447.53 of this subchapter.

(ii) Expenses incurred by the individual or family or financially responsible relatives for necessary medical and remedial services that are recognized under State law but not included in the plan.

(iii) Expenses incurred by the individual or family or by financially responsible relatives for necessary medical and remedial services that are included in the plan.

(2) The agency may set reasonable limits on the amounts of incurred medical expenses to be deducted from income under paragraphs (c)(1) (i) and (ii) of this section.

(d) *Eligibility based on incurred medical expenses.* Once deduction of incurred medical expenses reduces income to the income standard, the individual is eligible for Medicaid.

[43 FR 45204, Sept. 29, 1978, as amended at 45 FR 24886, Apr. 11, 1980; 46 FR 42067, Aug. 19, 1981; 46 FR 47988, Sept. 30, 1981]

§ 435.832 Post-eligibility treatment of income and resources of institutionalized individuals: Application of patient income to the cost of care.

(a) *Application of patient income.* The agency must reduce its payment to an institution, for services provided to an individual specified in paragraph (b) of this section, by the amount that remains after deducting the amounts specified in paragraphs (c) and (d) of this section, from the individual's total income, as determined in paragraph (e) of this section.

(b) *Applicability.* This section applies to medically needy individuals in medical institutions and intermediate care facilities.

(c) *Required deductions.* The agency must deduct the following amounts, in the following order, from the individual's total income, as determined under paragraph (e) of this section. Income that was disregarded in determining eligibility must be considered in this process.

(1) A personal needs allowance that is reasonable in amount for clothing and other personal needs of the individual while in the institution. This protected personal needs allowance must be at least—

(i) $25 a month for an aged, blind, or disabled individual, including a child applying for Medicaid on the basis of blindness or disability;

(ii) $50 a month for an institutionalized couple if both spouses are aged, blind, or disabled and their income is considered available to each other in determining eligibility; and

(iii) For other individuals, a reasonable amount set by the agency, based on a reasonable difference in their personal needs from those of the aged, blind, and disabled.

(2) For an individual with only a spouse at home, an additional amount for the maintenance needs of the spouse. This amount must be based on a reasonable assessment of need but must not exceed the highest of—

(i) The amount of the income standard used to determine eligibility for SSI for an individual living in his own home;

(ii) The amount of the highest income standard, in the appropriate category of age, blindness, or disability, used to determine eligibility for an optional State supplement for an individual in his own home, if the agency provides Medicaid to optional State supplement recipients under § 435.230; or

(iii) The amount of the highest medically needy income standards for one person established under § 435.814.

(3) For an individual with a family at home, an additional amount for the maintenance needs of the family. This amount must—

(i) Be based on a reasonable assessment of their financial need;

(ii) Be adjusted for the number of family members living in the home; and

(iii) Not exceed the highest of the following need standards for a family of the same size:

(A) The standard used to determine eligibility under the State's approved AFDC plan.

(B) The standards used to determine eligibility under the State's Medicaid plan, as provided for in § 435.814.

(4) Amounts for Medicare and other health insurance premiums, deductibles, or coinsurance charges that are not subject to payment by a third party.

(d) *Optional deductions.* In determining the amount of the individual's income to be used to reduce the agency's payment to the institution, the agency may deduct the following amounts from the individual's total income as determined under paragraph (e) of this section:

(1) Necessary medical or remedial services included in the State's Medicaid plan for the medically needy, which exceed limitations on amount, duration or scope imposed by the agency, subject to reasonable limits the agency may establish on amounts of these expenses;

(2) Necessary medical or remedial care recognized under State law but not covered under the State's Medicaid plan, subject to reasonable limits the agency may establish on amounts of these expenses; and

(3) For single individuals and couples, an amount (in addition to the personal needs allowance) for maintenance of the individual's or couple's home if—

(i) The amount is deducted for not more than a 6-month period; and

(ii) A physician has certified that either of the individuals is likely to return to the home within that period.

(e) *Determination of income*—(1) *Option.* In determining the amount of an individual's income to be used to reduce the agency's payment to the institution, the agency may use total income received or it may project total monthly income for a prospective period not to exceed 6 months.

(2) *Basis for projection.* The agency must base the projection on income received in the preceding period, not to exceed 6 months, and on income expected to be received.

(3) *Adjustments.* At the end of the prospective period specified in paragraph (e)(1) of this section, or when any significant change occurs, the agency must reconcile estimates with income received.

(f) *Determination of medical expenses*—(1) *Option.* In determining the amount of medical expenses to be deducted from an individual's income, the agency may deduct incurred medical expenses, or it may project medical expenses for a prospective period not to exceed 6 months.

(2) *Basis for projection.* The agency must base the estimate on medical expenses incurred in the preceding period, not to exceed 6 months, and medical expenses expected to be incurred.

(3) *Adjustments.* At the end of the prospective period specified in paragraph (f)(1) of this section, or when any significant change occurs, the agency must reconcile estimates with incurred medical expenses.

[45 FR 24886, Apr. 11, 1980, as amended at 46 FR 47988, Sept. 30, 1981; 48 FR 5735, Feb. 8, 1983; 53 FR 3596, Feb. 8, 1988; 53 FR 5344, Feb. 23, 1988]

MEDICALLY NEEDY RESOURCE STANDARDS

§ 435.840 Medically needy resource standards: General requirements.

To determine eligibility of medically needy individuals, a Medicaid agency must use a resource standard under this subpart that is—

(a) Based on family size;

(b) Uniform for all individuals in a group; and

(c) Reasonable. (See § 435.841)

[46 FR 47988, Sept. 30, 1981; 46 FR 54734, Nov. 11, 1981]

§ 435.841 Medically needy resource standards: Reasonableness.

(a) The agency must use a medically needy resource standard that is reasonable, according to the provisions of this section.

(b) The following medically needy resource standards are presumed to be reasonable:

(1) The agency provides one medically needy resource standard for all covered medically needy groups. Except as provided in paragraph (c) of this section, the standard must at least equal the highest resource standard used to determine eligibility in the cash assistance programs related to the covered medically needy groups.

(2) The agency provides a different medically needy resource standard for each covered medically needy group. Except as provided in paragraph (c) of this section, the standard for each covered group must at least equal the highest resource standard used to determine eligibility in the cash assistance program related to that covered medically needy group.

(c) In the case of an agency that provides Medicaid for the aged, blind, or disabled individuals only if they meet more restrictive requirements than used under SSI, the following provisions apply:

(1) The agency may use a resource standard for those individuals that is lower than the standard specified in paragraph (b) of this section.

(2) The lower standard must at least equal the medically needy resource standard for those aged, blind, or disabled individuals under the State's plan on January 1, 1972.

(d) If the agency uses a medically needy resource standard not specified in paragraphs (b) and (c) of this section—

(1) That standard is not presumed to be reasonable; and

(2) HCFA must approve the standard.

[46 FR 47988, Sept. 30, 1981; 46 FR 54743, Nov. 11, 1981]

§ 435.843 Medically needy resource standards: State plan requirements.

(a) The State plan must specify the resource standard for each covered medically needy group.

(b) If the agency uses a resource standard that is not presumed to be reasonable under § 435.841, the State plan must describe that standard.

[46 FR 47989, Sept. 30, 1981]

DETERMINING ELIGIBILITY ON THE BASIS OF RESOURCES

§ 435.845 Medically needy resource eligibility.

To determine eligibility on the basis of resources for medically needy individuals, the agency must—

(a) Consider only the individual's resources and those that are considered available to him under the financial responsibility requirements for relatives in § 435.821, § 435.822, or § 435.823;

(b) Consider only resources available during the period for which income is computed under § 435.831(a);

(c) For individuals under age 21 and caretaker relatives, deduct the value of resources that would be deducted in determining eligibility under the State's AFDC plan;

(d) For aged, blind, or disabled individuals in States covering all SSI recipients, deduct the value of resources that would be deducted in determining eligibility under SSI;

(e)(1) For aged, blind, or disabled individuals in States using requirements more restrictive than SSI, deduct the value of resources in an amount no more restrictive than those deducted under the Medicaid plan on January 1, 1972 and no more liberal than those deducted in determining eligibility under SSI.

(2) However, the amounts specified in paragraph (e)(1) of this section must be the same as those that would be deducted in determining, under § 435.121, the eligibility of the categorically needy; and

(f) Apply the resource standards established under § 435.843.

[43 FR 45204, Sept. 29, 1978, as amended at 45 FR 24886, Apr. 11, 1980; 46 FR 47989, Sept. 30, 1981]

TREATMENT OF INCOME AND RESOURCES

§ 435.850 Treatment of income and resources: General requirements.

To determine eligibility of medically needy individuals, a Medicaid agency must use a methodology for the treatment of income and resources that is—

(a) Uniform for all individuals in a covered group; and

(b) Reasonable (see § 435.851).

[46 FR 47989, Sept. 30, 1981]

§ 435.851 Treatment of income and resources: Reasonableness.

(a) The agency must use a methodology for the treatment of income and resources, to determine eligibility of the medically needy, that is reasonable.

(b) The methodology used to determine eligibility of individuals in the cash assistance program related to the covered medically needy group is presumed to be reasonable.

(c) If the agency provides Medicaid for the aged, blind, or disabled individuals who meet more restrictive requirements than used under SSI, the methodology for the treatment of income and resources of those aged, blind, or disabled individuals under the State's plan on January 1, 1972, is presumed to be reasonable.

(d) If the agency uses a methodology not described in paragraphs (b) and (c) of this section—

(1) The methodology is not presumed to be reasonable; and

(2) HCFA must approve that methodology.

[46 FR 47989, Sept. 30, 1981]

§ 435.852 Treatment of income and resources: State plan requirements.

(a) The State's plan must specify the methodology used to treat the income and resources for each covered medically needy group.

(b) If the agency uses a methodology that is not presumed to be reasonable under § 435.851, the State plan must describe that methodology.

[46 FR 47989, Sept. 30, 1981]

Subpart J—Eligibility in the States and District of Columbia

SOURCE: 44 FR 17937, Mar. 23, 1979, unless otherwise noted.

§ 435.900 Scope.

This subpart sets forth requirements for processing applications, determining eligibility, and furnishing Medicaid.

GENERAL METHODS OF ADMINISTRATION

§ 435.902 Consistency with objectives and statutes.

The Medicaid agency's standards and methods for determining eligibility must be consistent with the objectives of the program and with the rights of individuals under the United States Constitution, the Social Security Act, title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973, and all other relevant provisions of Federal and State laws.

§ 435.903 Simplicity of administration.

The agency's policies and procedures must ensure that eligibility is determined in a manner consistent with simplicity of administration and the best interests of the applicant or recipient.

§ 435.904 Adherence of local agencies to State plan requirements.

The agency must—

(a) Have methods to keep itself currently informed of the adherence of local agencies to the State plan provisions and the agency's procedures for determining eligibility; and

(b) Take corrective action to ensure their adherence.

APPLICATIONS

§ 435.905 Availability of program information.

(a) The agency must furnish the following information in written form, and orally as appropriate, to all applicants and to all other individuals who request it:

(1) The eligibility requirements.

(2) Available Medicaid services.

(3) The rights and responsibilities of applicants and recipients.

(b) The agency must publish in quantity and make available bulletins or pamphlets that explain the rules governing eligibility and appeals in simple and understandable terms.

[44 FR 17937, Mar. 23, 1979, as amended at 45 FR 24887, Apr. 11, 1980]

§ 435.906 Opportunity to apply.

The agency must afford an individual wishing to do so the opportunity to apply for Medicaid without delay.

§ 435.907 Written application.

The agency must require a written application from the applicant, an authorized representative or, if the applicant is incompetent or incapacitated, someone acting responsibly for the applicant. The application must be on a form prescribed by the agency and signed under a penalty of perjury.

§ 435.908 Assistance with application.

The agency must allow an individual or individuals of the applicant's choice to accompany, assist, and represent the applicant in the application process or a redetermination of eligibility.

§ 435.909 Automatic entitlement to Medicaid following a determination of eligibility under other programs.

The agency must not require a separate application for Medicaid from an individual, if—

(a) The individual receives AFDC; or

(b) The agency has an agreement with the Social Security Administration (SSA) under section 1634 of the Act for determining Medicaid eligibility; and—

(1) The individual receives SSI;

(2) The individual receives a mandatory State supplement under either a

federally-administered or State-administered program; or

(3) The individual receives an optional State supplement and the agency provides Medicaid to recipients of optional supplements under § 435.230.

§ 435.910 Use of social security number.

(a) The agency must require, as a condition of eligibility, that each individual (including children) requesting Medicaid services furnish each of his or her social security numbers (SSNs).

(b) The agency must advise the applicant of—

(1) [Reserved]

(2) The statute or other authority under which the agency is requesting the applicant's SSN; and

(3) The uses the agency will make of each SSN, including its use for verifying income, eligibility, and amount of medical assistance payments under §§ 435.940 through 435.960.

(c)—(d) [Reserved]

(e) If an applicant cannot recall his SSN or SSNs or has not been issued a SSN the agency must—

(1) Assist the applicant in completing an application for an SSN;

(2) Obtain evidence required under SSA regulations to establish the age, the citizenship or alien status, and the true identity of the applicant; and

(3) Either send the application to SSA or, if there is evidence that the applicant has previously been issued a SSN, request SSA to furnish the number.

(f) The agency must not deny or delay services to an otherwise eligible applicant pending issuance or verification of the individual's SSN by SSA.

(g) The agency must verify each SSN of each applicant and recipient with SSA, as prescribed by the Commissioner, to insure that each SSN furnished was issued to that individual, and to determine whether any others were issued.

[44 FR 17937, Mar. 23, 1979, as amended at 51 FR 7211, Feb. 28, 1986]

DETERMINATION OF MEDICAID ELIGIBILITY

§ 435.911 Timely determination of eligibility.

(a) The agency must establish time standards for determining eligibility and inform the applicant of what they are. These standards may not exceed—

(1) Sixty days for applicants who apply for Medicaid on the basis of disability; and

(2) Forty-five days for all other applicants.

(b) The time standards must cover the period from the date of application to the date the agency mails notice of its decision to the applicant.

(c) The agency must determine eligibility within the standards except in unusual circumstances, for example—

(1) When the agency cannot reach a decision because the applicant or an examining physician delays or fails to take a required action, or

(2) When there is an administrative or other emergency beyond the agency's control.

(d) The agency must document the reasons for delay in the applicant's case record.

(e) The agency must not use the time standards—

(1) As a waiting period before determining eligibility; or

(2) As a reason for denying eligibility (because it has not determined eligibility within the time standards).

[44 FR 17937, Mar. 23, 1979, as amended at 45 FR 24887, Apr. 11, 1980]

§ 435.912 Notice of agency's decision concerning eligibility.

The agency must send each applicant a written notice of the agency's decision on his application, and, if eligibility is denied, the reasons for the action, the specific regulation supporting the action, and an explanation of his right to request a hearing. (See Subpart E of Part 431 of this subchapter for rules on hearings.)

[44 FR 17937, Mar. 23, 1979, as amended at 51 FR 7211, Feb. 28, 1986]

§ 435.913 Case documentation.

(a) The agency must include in each applicant's case record facts to support the agency's decision on his application.

(b) The agency must dispose of each application by a finding of eligibility or ineligibility, unless—

(1) There is an entry in the case record that the applicant voluntarily withdrew the application, and that the agency sent a notice confirming his decision;

(2) There is a supporting entry in the case record that the applicant has died; or

(3) There is a supporting entry in the case record that the applicant cannot be located.

§ 435.914 Effective date.

(a) The agency must make eligibility for Medicaid effective no later than the third month before the month of application if the individual—

(1) Received Medicaid services, at any time during that period, of a type covered under the plan; and

(2) Would have been eligible for Medicaid at the time he received the services if he had applied (or someone had applied for him), regardless of whether the individual is alive when application for Medicaid is made.

(b) The agency may make eligiblity for Medicaid effective on the first day of a month if an individual was eligible at any time during that month.

(c) The State plan must specify the date on which eligibility will be made effective.

REDETERMINATIONS OF MEDICAID ELIGIBILITY

§ 435.916 Periodic redeterminations of Medicaid eligibility.

(a) The agency must redetermine the eligibility of Medicaid recipients, with respect to circumstances that may change, at least every 12 months, however—

(1) The agency may consider blindness as continuing until the review physician under § 435.531 determines that a recipient's vision has improved beyond the definition of blindness contained in the plan; and

(2) The agency may consider disability as continuing until the review team under § 435.541 determines that a recipient's disability no longer meets the definition of disability contained in the plan.

(b) *Procedures for reporting changes.* The agency must have procedures designed to ensure that recipients make timely and accurate reports of any change in circumstances that may affect their eligibility.

(c) *Agency action on information about changes.* (1) The agency must promptly redetermine eligibility when it receives information about changes in a recipient's circumstances that may affect his eligibility.

(2) If the agency has information about anticipated changes in a recipient's circumstances, it must redetermine eligibility at the appropriate time based on those changes.

§ 435.919 Timely and adequate notice concerning adverse actions.

(a) The agency must give recipients timely and adequate notice of proposed action to terminate, discontinue, or suspend their eligibility or to reduce or discontinue services they may receive under Medicaid.

(b) The notice must meet the requirements of Subpart E of Part 431 of this subchapter.

[44 FR 17937, Mar. 23, 1979, as amended at 45 FR 24887, Apr. 11, 1980; 51 FR 7211, Feb. 28, 1986]

§ 435.920 Verification of SSNs.

(a) In redetermining eligibility, the agency must review case records to determine whether they contain the recipient's SSN or, in the case of families, each family member's SSN.

(b) If the case record does not contain the required SSNs, the agency must require the recipient to furnish them and meet other requirements of § 435.910.

(c) For any recipient whose SSN was established as part of the case record without evidence required under the SSA regulations as to age, citizenship, alien status, or true identity, the agency must obtain verification of these factors in accordance with § 435.910.

[44 FR 17937, Mar. 23, 1979, as amended at 51 FR 7211, Feb. 28, 1986]

FURNISHING MEDICAID

§ 435.930 Furnishing Medicaid.

The agency must—

(a) Furnish Medicaid promptly to recipients without any delay caused by the agency's administrative procedures;

(b) Continue to furnish Medicaid regularly to all eligible individuals until they are found to be ineligible; and

(c) Make arrangements to assist applicants and recipients to get emergency medical care whenever needed, 24 hours a day and 7 days a week.

INCOME AND ELIGIBILITY VERIFICATION REQUIREMENTS

SOURCE: Sections 435.940 through 935.965 appear at 51 FR 7211, Feb. 28, 1986, unless otherwise noted.

§ 435.940 Basis and scope.

(a) Section 1137 of the Act requires certain Federally-funded, State-administered public assistance programs to establish procedures for obtaining, using and verifying information relevant to determinations as to eligibility and the amount of assistance. Section 1902(a)(4) of the Act allows the Secretary to prescribe methods of administration found necessary for the proper and efficient operation of a State's Medicaid plan.

(b) The agency must maintain information, as enumerated in § 435.960, to exchange for the purpose of enabling any agency or program referenced in § 435.945(b) to verify income, eligibility of, and the amount of assistance for its applicants and recipients.

§ 435.945 General requirements.

(a) The agency must request and use information timely in accordance with §§ 435.948 and 435.952 of this subpart for verifying Medicaid eligibility and the amount of medical assistance payments.

(b) The agency must furnish timely to other agencies in the State and in other States and to Federal programs income, eligibility and medical assistance payment information for verifying eligibility or benefit amounts for the programs listed in § 435.948(a)(6) of this subpart. In addition, the agency must furnish income and eligibility information to—

(1) The child support enforcement program under part D of title IV of the Act; and

(2) SSA for old age, survivors and disability benefits under title II and for SSI benefits under title XVI of the Act.

(c) The agency must, upon request, reimburse another agency listed in § 435.948(a)(6) of this subpart or paragraph (b) of this section for reasonable costs incurred in furnishing information, including new developmental costs associated with furnishing the information to another agency.

(d) The agency must inform all applicants in writing at the time of application that the agency will obtain and use information available to it under section 1137 of the Act to verify income, eligibility and the correct amount of medical assistance payments. The agency must give each recipient the same notice when it redetermines eligibility. The requirements in this paragraph do not apply in the case of applicants or recipients whose eligibility is determined by AFDC or by SSA under section 1634 of the Act.

(e) The agency must report as the Secretary prescribes for the purposes of determining compliance with §§ 431.305, 431.800, 435.910, 435.919 and 435.940 through 435.965 of this chapter and of evaluating the effectiveness of the income and eligibility verification system.

(f) The agency must execute written agreements with other agencies before releasing data to or requesting data from, those agencies. The agreements, at a minimum, must specify:

(1) The information to be exchanged;

(2) The titles of all agency officials with the authority to request income and eligibility information;

(3) The methods, including the formats to be used, and the timing for requesting and providing the information (see also paragraph (f)(6) of this section);

(4) The safeguards limiting the use and disclosure of the information as required by Federal or State law or regulations;

(5) The method, if any, the agency will use to reimburse reasonable costs of furnishing the information; and

(6) In the case of an agreement between a SWICA or a UC agency and the Medicaid agency, that the Medicaid agency will obtain information on applicants at least twice monthly.

(g) SWICA that does not use the quarterly wages reported by employers as required by Section 1137 of the Act of unemployment insurance benefit calculations must maintain wage information that:

(1) Contains the SSN, full name, wages earned for the period of the report, and an identifier of the employer;

(2) Includes all employers covered by the States' UC law;

(3) Accumulates earnings reported by employers for no longer periods than calendar quarters;

(4) Is reported to the SWICA within 30 days after the end of the quarter;

(5) Is machine readable; and

(6) Is accessible to agencies in other States that have executed agreements as required in § 435.945(f) of this chapter and to SSA for use in making eligibility or benefit determinations under Title II or XVI of the Act.

[51 FR 7211, Feb. 28, 1986, as amended at 52 FR 5977, Feb. 27, 1987]

§ 435.948 Requesting information.

(a) Except as provided in paragraphs (d), (e), and (f) of this section, the agency must request information from the sources specified in this paragraph for verifying Medicaid eligibility and the correct amount of medical assistance payments for each applicant (unless obviously ineligible on the face of his or her application) and recipient. The agency must request—

(1) State wage information maintained by the SWICA during the application period and at least on a quarterly basis;

(2) Information about net earnings from self-employment, wage and payment of retirement income, maintained by SSA and available under Section 6103(l)(7)(A) of the Internal Revenue Code of 1954, for applicants during the application period and for recipients for whom the information has not previously been requested;

(3) Information about benefit and other eligibility related information available from SSA under titles II and XVI of the Social Security Act for applicants during the application period and for recipients for whom the information has not previously been requested;

(4) Unearned income information from the Internal Revenue Service available under Section 6103(l)(7)(B) of the Internal Revenue Code of 1954, during the application period and at least yearly;

(5) Unemployment compensation information maintained by the agency administering State unemployment compensation laws (under the provisions of section 3304 of the Internal Revenue Code and section 303 of the Act) as follows:

(i) For an applicant, during the application period and at least for each of the three subsequent months;

(ii) For a recipient that reports a loss of employment, at the time the recipient reports that loss and for at least each of the three subsequent months.

(iii) For an applicant or a recipient who is found to be receiving unemployment compensation benefits, at least for each month until the benefits are reported to be exhausted.

(6) Any additional income, resource, or eligibility information relevant to determinations concerning eligibility or correct amount of medical assistance payments available from agencies in the State or other States administering the following programs as provided in the agency's State plan:

(i) AFDC;

(ii) Medicaid;

(iii) State-administered supplementary payment programs under Section 1616(a) of the Act;

(iv) SWICA;

(v) Unemployment compensation;

(vi) Food stamps; and

(vii) Any State program administered under a plan approved under Title I (assistance to the aged), X (aid to the blind), XIV (aid to the permanently and totally disabled), or XVI (aid to the aged, blind, and disabled in Puerto Rico, Guam, and the Virgin Islands) of the Act.

(b) The agency must request information on applicants from the sources listed in paragraph (a)(1) through (a)(5) of this section at the first opportunity provided by these sources following the receipt of the application. If an applicant cannot provide an SSN at application, the agency must request the information at the next available opportunity after receiving the SSN.

(c) The agency must request the information required in paragraph (a) of this section by SSN, using each SSN furnished by the individual or received through verification.

(d) *Exception*: In cases where the individual is institutionalized, the agency needs to obtain and use information from SWICA only during the application period and on a yearly basis, and from unemployment compensation agencies only during the application period. An individual is institutionalized for purposes of this section when he or she is required to apply his or her income to the cost of medical care as required by §§ 435.725, 435.733, and 435.832.

(e) *Exception*: *Alternate sources.* (1) The Secretary may, upon application from a State agency, permit an agency to request and use income information from a source or sources alternative to those listed in paragraph (a) of this section. The agency must demonstrate to the Secretary that the alternative source(s) is as timely, complete and useful for verifying eligibility and benefit amounts. The Secretary will consult with the Secretary of Agriculture and the Secretary of Labor before determining whether an agency may use an alternate source.

(2) The agency must continue to meet the requirements of this section unless the Secretary has approved the request.

(f) *Exception:* If the agency administering the the AFDC program, or SSA under section 1634 of the Act, determines the eligibility of an applicant or recipient, the requirements of this section do not apply to that applicant or recipient.

§ 435.952 Use of information.

(a) The agency must review and compare against the casefile any information received under §§ 435.940 through 435.960 to determine whether it affects the applicant's or recipient's eligibility or amount of medical assistance payment. The agency must also verify the information if determined appropriate by agency experience or if required by § 435.955.

(b) For applicants, if the information is received during the application period, it must be used, to the extent possible, making eligibility determinations. If it is received after the eligibility determination, it must be used as specified for recipients in paragraphs (c) and (d) of this section.

(c) Except as specified in paragraph (d) of this section, for recipients, the agency must, within 30 days of receipt of an item of information, request verification (if appropriate), determine whether the information affects eligibility or the amount of medical assistance payment, and make an entry in the case file that no action is necessary or notify the recipient of any adverse action the agency intends to take.

(d) Subject to paragraph (e) of this section, if the agency does not receive requested third party verification within the 30 day period after receipt of information, the agency may determine whether the information affects eligibility or correct amount of medical assistance payment after the 30 day period. However, the agency must make any delayed determinations permitted under this paragraph—

(1) Promptly, as required by § 435.916, if the verification is received before the next redetermination; or

(2) In conjunction with the next redetermination if no verification is received before that redetermination.

(e) The number of determinations delayed beyond 30 days from receipt of an item of information (as permitted by paragraph (d) of this section) must not exceed twenty percent of the number of items of information received on all recipients.

(f) The agency must use appropriate procedures to monitor the timeliness requirements of this section.

(g) The requirements of this section do not relieve the agency of its responsibility for determinations of erroneous payments or the agency's liability for those erroneous payments, as defined in Subpart P of Part 431 of this chapter.

[51 FR 7211, Feb. 28, 1986, as amended at 53 FR 6648, March 2, 1988]

§ 435.955 Additional requirements regarding the use of information released by the Department of the Treasury.

(a) Based on information concerning an applicant's or recipient's unearned income the agency receives from the Department of Treasury (Internal Revenue Service) (under section 6103(l)(7)(B) of the Internal Revenue Code of 1954), the agency may not terminate, deny, suspend, or reduce benefits to that individual until it has taken appropriate steps to verify the information, independently, relating to—

(1) The amount of the income and resource that generated the income involved;

(2) Whether the applicant or recipient actually has (or had) access to the resource of income (or both) for his or her own use; and

(3) The period or periods when the individual actually had the resource or income or both.

(b) The agency must verify the information by either—

(1) Requesting the entity from which the individual received the unearned income to verify the fact and amount of the unearned income and resource that generated the income; or

(2) Sending the applicant or recipient a letter informing that individual of the information received and asking him or her to respond within a specified period. The letter must clearly explain the information the agency has and its possible relevance to the individual's past or future eligibility, and be as neutral in tone as possible.

(c)(1) If the source of the unearned income or the applicant or recipient verifies the information, and the agency intends to reduce, suspend, terminate or deny medical assistance payments based on the information, the agency must send the applicant or recipient a notice of the action to be taken and include information on the right to appeal and opportunity for a hearing under §§ 431.200 through 431.250 of this chapter (see also § 435.912 and § 435.919).

(2) If the applicant or recipient fails to respond after reasonable attempts to contact him or her, the agency must proceed to deny, terminate, reduce or suspend benefits based on the applicant's or recipient's failure to cooperate.

(3) If the applicant or recipient disputes the information, the agency must obtain evidence (from the source of the unearned income, applicant or recipient, or otherwise) to substantiate any negative case action that it may take.

§ 435.960 Standardized formats for furnishing and obtaining information to verifying income and eligibility.

(a) The agency must maintain for all applicants and recipients within an agency file the SSN, surname and other data elements in a format that at a minimum allows the agency to furnish and to obtain eligibility and income information from the agencies or programs referenced in § 435.945(b) and § 435.948(a).

(b) The format to be used will be prescribed by—

(1) HCFA when the agency furnishes information to, or requests information from, any Federal or State agency, except SSA and the Internal Revenue Service as specified in paragraphs (b) (2) and (3), respectively;

(2) The Commissioner of Social Security when the agency requests information from SSA; and

(3) The Commissioner of Internal Revenue when the agency requests information from the Internal Revenue Service.

[52 FR 5977, Feb. 27, 1987]

§ 435.965 Delay of effective date.

(a) If the agency submits, by May 29, 1986, a plan describing a good faith effort to come into compliance with the requirements of section 1137 of the Act and of §§ 435.910 and 435.940 through 435.960 of this subpart, the Secretary may, after consultation with the Secretary of Agriculture and the Secretary of Labor, grant a delay in the effective date of §§ 435.910 and 435.940 through 435.960, but not beyond September 30, 1986.

(b) The Secretary may not grant a delay of the effective date of section 1137(c) of the Act, which is implemented by § 435.955 (a) and (c). (The provisions of these statutory and regulation sections require the agency to follow certain procedures before taking any adverse actions based on information from the Internal Revenue Service concerning unearned income.)

Subpart K—Federal Financial Participation

§ 435.1000 Scope.

This subpart specifies when, and the extent to which, FFP is available in expenditures for determining eligibility and for Medicaid services to individuals determined eligible under this part, and prescribes limitations and conditions on FFP for those expenditures.

FFP IN EXPENDITURES FOR DETERMINING ELIGIBILITY AND PROVIDING SERVICES

§ 435.1001 FFP for administration.

(a) FFP is available in the necessary administrative costs the State incurs in determining and redetermining Medicaid eligibility and in providing Medicaid to eligible individuals.

(b) Administrative costs include any costs incident to an eye examination or medical examination to determine whether an individual is blind or disabled.

§ 435.1002 FFP for services.

(a) Except for the limitations and conditions specified in §§ 435.1007 and 435.1008, FFP is available in expenditures for Medicaid services for all recipients whose coverage is required or allowed under this part.

(b) FFP is available in expenditures for services provided to recipients who were eligible for Medicaid in the month in which the medical care or services were provided except that, for recipients who establish eligibility for Medicaid by deducting incurred medical expenses from income, FFP is not available for expenses that are the recipient's liability. (See § 435.914 and § 436.901 of this subchapter for regulations on retroactive eligibility for Medicaid.)

[43 FR 45204, Sept. 29, 1978, as amended at 44 FR 17939, Mar. 23, 1979]

§ 435.1003 Recipients determined ineligible for SSI.

(a) If the Social Security Administration (SSA) notifies an agency that a recipient has been determined ineligible for SSI, FFP is available in Medicaid expenditures for services to the recipient as follows:

(1) If the agency receives the SSA notice by the 10th day of the month, FFP is available under this section only through the end of the month unless the recipient requests a hearing under Subpart E, Part 431 of this subchapter.

(2) If the agency receives the SSA notice after the 10th day of the month, FFP is available only through the end of the following month, unless the recipient requests a hearing under Subpart E, Part 431 of this subchapter.

(3) If a recipient requests a hearing, FFP is available as specified in Subpart E, Part 431 of this subchapter.

(b) The agency must take prompt action to determine eligibility after receiving the SSA notice.

[43 FR 45204, Sept. 29, 1978, as amended at 44 FR 17939, Mar. 23, 1979]

§ 435.1004 Recipients overcoming certain conditions of eligibility.

(a) FFP is available, as specified in paragraph (b) of this section, in expenditures for services provided to recipients who are overcoming certain eligibility conditions, including blindness, disability, continued absence or incapacity of a parent, or unemployment of a parent.

(b) FFP is available for a period not to exceed—

(1) The period during which a recipient of AFDC, SSI or an optional State supplement continues to receive cash payments while these conditions are being overcome; or

(2) For recipients eligible for Medicaid only and recipients of AFDC, SSI or an optional State supplement who do not continue to receive cash payments, the second month following

the month in which the recipient's Medicaid eligibility would have been terminated.

[43 FR 45204, Sept. 29, 1978, as amended at 45 FR 24887, Apr. 11, 1980]

LIMITATIONS ON FFP

§ 435.1005 Recipients in institutions eligible under special outside standard.

For recipients in institutions whose Medicaid eligibility is based on a special income standard established under § 435.231, FFP is available in expenditures for services provided to those individuals only if their income before deductions does not exceed 300 percent of the SSI benefit amount payable under section 1611(b)(1) of the Act to an individual in his own home who has no income or resources.

§ 435.1006 Recipients of optional State supplements only.

FFP is available in expenditures for services provided to individuals receiving optional State supplements but not receiving SSI, if their income before deductions, as determined by SSI budget methodology, does not exceed 300 percent of the SSI benefit amount payable under section 1611(b)(1) of the Act to an individual who has no income and resources.

[45 FR 24887, Apr. 11, 1980]

§ 435.1007 Medically needy.

(a) FFP is available in expenditures for services provided to medically needy recipients whose annual income after deductions specified in § 436.831 (a) and (c) and § 436.832 does not exceed the following amounts, rounded to the next higher multiple of $100:

(1) For couples and families of two or more, 133⅓ percent of the highest money payment that would ordinarily be made under the State's AFDC plan to a family of the same size without income and resources. If the State's AFDC plan specifies a maximum family size beyond which there is no increase in benefits, the medically needy income levels for families whose size exceeds that maximum will be determined by adding an amount for each family member over the maximum size. These amounts must be reasonably related to the amounts by which the State's AFDC plan increases benefits for additional family members in families below the maximum size.

(2) For individuals, 133⅓ percent of an amount reasonably related to the highest money payment which would ordinarily be made under the State's AFDC plan to a family of two without income and resources.

§ 435.1008 Institutionalized individuals.

(a) FFP is not available in expenditures for services provided to—

(1) Individuals who are inmates of public institutions as defined in § 435.1009; or

(2) Individuals under age 65 who are patients in an institution for mental diseases unless they are under age 22 and are receiving inpatient psychiatric services under § 440.160 of this subchapter.

(b) The exclusion of FFP described in paragraph (a) of this section does not apply during that part of the month in which the individual is not an inmate of a public institution or a patient in an institution for tuberculosis or mental diseases.

(c) An individual on conditional release or convalescent leave from an institution for mental diseases is not considered to be a patient in that institution. However, such an individual who is under age 22 and has been receiving inpatient psychiatric services under § 440.160 of this subchapter is considered to be a patient in the institution until he is unconditionally released or, if earlier, the date he reaches age 22.

[43 FR 45204, Sept. 29, 1978, as amended at 50 FR 13199, Apr. 3, 1985; 50 FR 38811, Sept. 25, 1985]

§ 435.1009 Definitions relating to institutional status.

For purposes of FFP, the following definitions apply:

Active treatment in intermediate care facilities for the mentally retarded means treatment that meets the requirements specified in the standard concerning active treatment for intermediate care facilities for persons with mental retardation under § 483.440(a) of this subchapter.

Child-care institution means a nonprofit private child-care institution, or a public child-care institution that accommodates no more than twenty-five children, which is licensed by the State in which it is situated, or has been approved by the agency of the State responsible for licensing or approval of institutions of this type, as meeting the standards established for licensing. The term does not include detention facilities, forestry camps, training schools or any other facility operated primarily for the detention of children who are determined to be delinquent.

In an institution refers to an individual who is admitted to live there and receive treatment or services provided there that are appropriate to his requirements.

Inmate of a public institution means a person who is living in a public institution. An individual is not considered an inmate if—

(a) He is in a public educational or vocational training institution for purposes of securing education or vocational training; or

(b) He is in a public institution for a temporary period pending other arrangements appropriate to his needs.

Inpatient means a patient who has been admitted to a medical institution as an inpatient on recommendation of a physician or dentist and who—

(1) Receives room, board and professional services in the institution for a 24 hour period or longer, or

(2) Is expected by the institution to receive room, board and professional services in the institution for a 24 hour period or longer even though it later develops that the patient dies, is discharged or is transferred to another facility and does not actually stay in the institution for 24 hours.

Institution means an establishment that furnishes (in single or multiple facilities) food, shelter, and some treatment or services to four or more persons unrelated to the proprietor.

Institution for mental diseases means an institution that is primarily engaged in providing diagnosis, treatment or care of persons with mental diseases, including medical attention, nursing care and related services. Whether an institution is an institution for mental diseases is determined by its overall character as that of a facility established and maintained primarily for the care and treatment of individuals with mental diseases, whether or not it is licensed as such. An institution for the mentally retarded is not an institution for mental diseases.

Institution for the mentally retarded or persons with related conditions means an institution (or distinct part of an institution) that—

(a) Is primarily for the diagnosis, treatment, or rehabilitation of the mentally retarded or persons with related conditions; and

(b) Provides, in a protected residential setting, ongoing evaluation, planning, 24-hour supervision, coordination, and integration of health or rehabilitative services to help each individual function at his greatest ability.

Institution for tuberculosis means an institution that is primarily engaged in providing diagnosis, treatment, or care of persons with tuberculosis, including medical attention, nursing care, and related services. Whether an institution is an institution for tuberculosis is determined by its overall character as that of a facility established and maintained primarily for the care and treatment of tuberculosis, whether or not it is licensed as such.

Medical institution means an institution that—

(a) Is organized to provide medical care, including nursing and convalescent care;

(b) Has the necessary professional personnel, equipment, and facilities to manage the medical, nursing, and other health needs of patients on a continuing basis in accordance with accepted standards;

(c) Is authorized under State law to provide medical care; and

(d) Is staffed by professional personnel who are responsible to the institution for professional medical and nursing services. The services must include adequate and continual medical care and supervision by a physician; registered nurse or licensed practical nurse supervision and services and nurses' aid services, sufficient to meet nursing care needs; and a physician's guidance on the professional aspects of operating the institution.

Outpatient means a patient of an organized medical facility or distinct part of that facility who is expected by the facility to receive, and who does receive, professional services for less than a 24-hour period regardless of the hour of admission, whether or not a bed is used or whether or not the patient remains in the facility past midnight.

Patient means an individual who is receiving needed professional services that are directed by a licensed practitioner of the healing arts toward maintenance, improvement, or protection of health, or lessening of illness, disability, or pain.

Persons with related conditions means individuals who have a severe, chronic disability that meets all of the following conditions:

(a) It is attributable to—

(1) Cerebral palsy or epilepsy; or

(2) Any other condition, other than mental illness, found to be closely related to mental retardation because this condition results in impairment of general intellectual functioning or adaptive behavior similar to that of mentally retarded persons, and requires treatment or services similar to those required for these persons.

(b) It is manifested before the person reaches age 22.

(c) It is likely to continue indefinitely.

(d) It results in substantial functional limitations in three or more of the following areas of major life activity:

(1) Self-care.

(2) Understanding and use of language.

(3) Learning.

(4) Mobility.

(5) Self-direction.

(6) Capacity for independent living.

Public institution means an institution that is the responsibility of a governmental unit or over which a governmental unit exercises administrative control. The term "public institution" does not include

(a) A medical institution as defined in this section;

(b) An intermediate care facility as defined in §§ 440.140 and 440.150 of this chapter;

(c) A publicly operated community residence that serves no more than 16 residents, as defined in this section; or

(d) A child-care institution as defined in this section with respect to

(1) Children for whom foster care maintenance payments are made under title IV-E of the Act; and

(2) Children receiving AFDC—foster care under title IV-A of the Act.

Publicly operated community residence that serves no more than 16 residents is defined in 20 CFR 416.231(b)(6)(i). A summary of that definition is repeated here for the information of readers.

(a) In general, a publicly operated community residence means—

(1) It is publicly operated as defined in 20 CFR 416.231(b)(2).

(2) It is designed or has been changed to serve no more than 16 residents and it is serving no more than 16; and

(3) It provides some services beyond food and shelter such as social services, help with personal living activities, or training in socialization and life skills. Occasional medical or remedial care may also be provided as defined in 45 CFR 228.1; and

(b) A publicly operated community residence does not include the following facilities, even though they accommodate 16 or fewer residents:

(1) Residential facilities located on the grounds of, or immediately adjacent to, any large institution or multiple purpose complex.

(2) Educational or vocational training institutions that primarily provide an approved, accredited, or recognized program to individuals residing there.

(3) Correctional or holding facilities for individuals who are prisoners, have been arrested or detained pending disposition of charges, or are held under court order as material witnesses or juveniles.

(4) Hospitals, skilled nursing facilities, and intermediate care facilities.

Resident of an intermediate care facility is an individual who is—

(a) In need of and receiving professional services to maintain, improve, or protect health or lessen disability or pain under the direction of a practitioner of the healing arts;

(b) Admitted to an intermediate care facility in accordance with §§ 450.370 through 450.381 of this subchapter, or receiving ICF services in a hospital with a swing-bed approval in accordance with § 447.280 of this chapter;

(c) Under care and supervision 24 hours a day; and

(d) If he or she is in an institution for the mentally retarded, receiving active treatment as defined in this section.

[43 FR 45204, Sept. 29, 1978, as amended at 47 FR 28655, July 1, 1982; 47 FR 31532, July 20, 1982; 51 FR 19181, May 28, 1986; 52 FR 47934, Dec. 17, 1987; 53 FR 657, Jan. 11, 1988; 53 FR 20495, June 3, 1988]

EFFECTIVE DATE NOTE: At 53 FR 20495, June 3, 1988, § 435.1009 was amended by revising the definition of "Active treatment in institutions for the mentally retarded", effective October 3, 1988. For the convenience of the user, the superseded text is set forth as follows:

§ 435.1009 Definitions relating to institutional status.

* * * * *

Active treatment in institutions for the mentally retarded requires the following:

(a) The individual's regular participation, in accordance with an individual plan of care, in professionally developed and supervised activities, experiences, or therapies.

(b) An individual written plan of care that sets forth measurable goals or objectives stated in terms of desirable behavior and that prescribes an integrated program of activities, experiences or therapies necessary for the individual to reach those goals or objectives. The overall purpose of the plan is to help the individual function at the greatest physical, intellectual, social, or vocational level he can presently or potentially achieve.

(c) An interdisciplinary professional evaluation that—

(1) Is completed, for a recipient, before admission to the institution but not more than 3 months before and, for an individual applying for Medicaid after admission, before the institution requests payment;

(2) Consists of complete medical, social, and psychological diagnosis and evaluations and an evaluation of the individual's need for institutional care; and

(3) Is made by a physician, a social worker and other professionals, at least one of whom is a qualified mental retardation professional as defined in § 442.401 of this subchapter.

(d) Reevaluation medically, socially, and psychologically at least annually by the staff involved in carrying out the resident's individual plan of care. This must include review of the individual's progress toward meeting the plan objectives, the appropriateness of the individual plan of care, assessment of his continuing need for institutional care, and consideration of alternate methods of care.

(e) An individual postinstitutionalization plan, as part of the individual plan of care, developed before discharge by a qualified mental retardation professional and other appropriate professionals. This must include provision for appropriate services, protective supervision, and other follow-up services in the resident's new environment.

* * * * *

REQUIREMENTS FOR STATE SUPPLEMENTS

§ 435.1010 Requirement for mandatory State supplements.

(a) Except as specified in paragraph (b) of this section, FFP is not available in Medicaid expenditures in any quarter in which the State does not have in effect an agreement with the Secretary under section 212 of Pub. L. 93-66 (July 9, 1973) for minimum mandatory State supplements of the basic SSI benefit.

(b) This section does not apply to any State that meets the conditions of section 212(f) of Pub. L. 93-66.

§ 435.1011 Requirement for maintenance of optinal State supplement expenditures.

(a) This section applies to States that make optional State supplement payments under section 1616(a) of the Act and mandatory supplement payments under section 212(a) of Pub. L. 93-66.

(b) FFP in Medicaid expenditures is not available in the following periods, if the State does not have in effect an agreement with the Secretary under section 1618 of the Act to maintain its December 1976 supplementary payment expenditure levels:

(1) Any calendar quarter after June 30, 1977; or

(2) If later, any calendar quarter after the one in which the State first makes supplementary payments.

PART 436—ELIGIBILITY IN GUAM, PUERTO RICO, AND THE VIRGIN ISLANDS

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AUTHORITY: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

SOURCE: 43 FR 45218, Sept. 29, 1978, unless otherwise noted.

Subpart A—General Provisions and Definitions

§ 436.1 Purpose and applicability.

This part sets forth, for Guam, Puerto Rico, and the Virgin Islands—

(a) The eligibility provisions that a State plan must contain;

(b) The mandatory and optional groups of individuals to whom Medicaid is provided under a State plan;

(c) The eligibility requirements and procedures that a Medicaid agency must use in determining and redetermining eligibility, and requirements it may not use; and

(d) The availability of FFP for providing Medicaid and for administering the eligibility provisions of the plan.

[43 FR 45218, Sept. 29, 1978, as amended at 44 FR 17939, Mar. 23, 1979]

§ 436.2 Basis.

This part implements the following sections of the Act and public laws which state requirements and standards for eligibility:

402(a)(22) Eligibility of deemed recipients of AFDC who receive zero payments because of recoupment of overpayments.
402(a)(37) Eligibility of individuals who lose AFDC eligibility due to increased earnings.
414(g) Eligibility of certain individuals participating in work supplementation programs.
1902(a)(8) Opportunity to apply; assistance must be furnished promptly.
1902(a)(10) Required and optional groups.
1902(a)(12) Determination of blindness.

1902(a)(16) Out-of-State care for State residents.

1902(a)(17) Standards for determining eligibility; flexibility in the application of income eligibility standards.

1902(a)(19) Safeguards for simplicity of administration and best interests of recipients.

1902(a)(34) Three-month retroactive eligibility.

1902(a) (second paragraph after (47)) Eligibility despite increased monthly insurance benefits under title II.

1902(b) Prohibited conditions for eligibility:

Age requirements of more than 65 years;

State residence requirements excluding individuals who reside in the State; and

Citizenship requirement excluding United States citizens.

1902(e) Four-month continued eligibility for families ineligible because of increased hours or income from employment.

1902(e)(2) Minimum eligibility period for recipients enrolled in HMO.

1902(e)(4) Eligibility of newborn children of Medicaid-eligible women.

1905(a) (i)-(viii) List of eligible individuals.

1905(a) (clause following (21)) Prohibitions against providing Medicaid to certain institutionalized individuals.

1905(a) (second sentence) Definition of essential person.

1905(d)(2) Definition of resident of an intermediate care facility for the mentally retarded.

1905(n) Definition of qualified pregnant woman and child.

1915(c) Home or community based services.

412(e)(5) of Immigration and Nationality Act-Eligibility of certain refugees.

Pub. L. 93-66, section 230 Deemed eligibility of certain essential persons.

Pub. L. 93-66, section 231 Deemed eligibility of certain persons in medical institutions.

Pub. L. 93-66, section 232 Deemed eligibility of certain blind and disabled medically indigent persons.

Pub. L. 96-272, section 310(b)(1) Continued eligibility of certain recipients of Veterans Administration pensions.

[52 FR 43072, Nov. 9, 1987; 52 FR 48438, Dec. 22, 1987]

§ 436.3 Definitions and use of terms.

As used in this part—

AABD means aid to the aged, blind, and disabled under title XVI of the Act;

AB means aid to the blind under title X of the Act;

AFDC means aid to families with dependent children under title IV-A of the Act;

APTD means aid to the permanently and totally disabled under title XIV of the Act;

Categorically needy means aged, blind, or disable individuals or families and children

(a) Who are otherwise eligible for Medicaid and who meet the financial eligibility requirements for OAA, AFDC, AB, APTD, or AABD; or,

(b) Whose categorical eligibility is protected by statute (e.g., persons who received increased OASDI payments. See § 436.112).

Families and children refers to eligible members of families with children who are financially eligible under AFDC or medically needy rules and who are deprived of parental support or care as defined under the AFDC program (see 45 CFR 233.90; 233.100). In addition, this group includes individuals under age 21 who are not deprived of parental support or care but who are financially eligible under AFDC or medically needy rules (see optional coverage group, § 436.222);

Medically needy means aged, blind, or disabled individuals or families and children who are otherwise eligible for Medicaid, who are not categorically needy and whose income and resources are within limits set under the Medicaid State plan.

OAA means old age assistance under title I of the Act;

OASDI means old age, survivors, and disability insurance under Title II of the Act.

[43 FR 45218, Sept. 29, 1978, as amended at 45 FR 24887, Apr. 11, 1980; 46 FR 47989, Sept. 30, 1981]

§ 436.10 State plan requirements.

A State plan must—

(a) Provide that the requirements of this part are met; and

(b) Specify the groups to whom Medicaid is provided, as specified in Subparts B, C, and D of this part, and the conditions of eligibility for individuals in those groups.

Subpart B—Mandatory Coverage of the Categorically Needy

§ 436.100 Scope.

This subpart prescribes requirements for coverage of categorically needy individuals.

§ 436.110 Individuals receiving cash assistance.

(a) A Medicaid agency must provide Medicaid to individuals receiving cash assistance under OAA, AFDC, AB, APTD, or AABD.

(b) For purposes of this section, an individual is receiving cash assistance if his needs are considered in determining the amount of the payment. This includes an individual whose presence in the home is considered essential to the well-being of a recipient under the State's plan for OAA, AFDC, AB, APTD, or AABD if that plan were as broad as allowed under the Act for FFP.

§ 436.111 Individuals who are not eligible for cash assistance because of a requirement not applicable under Medicaid.

The agency must provide Medicaid to individuals who would be eligible for OAA, AFDC, AB, APTD, or AABD except for an eligibility requirement used in those programs that is specifically prohibited under title XIX.

[47 FR 43648, Oct. 1, 1982]

Editorial Note: Section 436.111 was revised at 47 FR 43648, Oct. 1, 1982. The reporting and/or recordkeeping requirements contained in this section are not effective until OMB approval has been obtained.

§ 436.112 Individuals who would be eligible for cash assistance except for increased OASDI under Pub. L. 92-336 (July 1, 1972).

The agency must provide Medicaid to individuals who meet the following conditions:

(a) In August 1972, the individual was entitled to OASDI and—

(1) He was receiving cash assistance; or

(2) He would have been eligible for cash assistance if he had applied, and the Medicaid plan covered this optional group; or

(3) He would have been eligible for cash assistance if he were not in a medical institution or intermediate care facility, and the Medicaid plan covered this optional group.

(b) The individual would currently be eligible for cash assistance except that the increase in OASDI under Pub. L. 92-336 raised his income over the limit allowed under the cash assistance program. This includes an individual who—

(1) Meets all current requirements for cash assistance except for the requirement to file an application; or

(2) Would meet all current requirements for cash assistance if he were not in a medical institution or intermediate care facility, and the Medicaid plan covers this optional group.

§ 436.114 Individuals deemed to be receiving AFDC.

(a) The Medicaid agency must provide Medicaid to individuals deemed to be receiving AFDC, as specified in this section.

(b) The State must deem individuals to be receiving AFDC who are denied a cash payment from the title IV-A State agency solely because the amount of the AFDC payment would be less than $10.

(c) The State may deem participants in a work supplementation program to be receiving AFDC under section 414(g) of the Act. This section permits States, for purposes of title XIX, to deem an individual and any child or relative of the individual (or other individual living in the same household) to be receiving AFDC, if the individual—

(1) Participates in a State-operated work supplementation program under section 414 of the Act; and

(2) Would be eligible for an AFDC cash payment if the individual were not participating in the work supplementation program.

(d) The State must deem to be receiving AFDC those individuals who are denied AFDC payments from the title IV-A State agency solely because that agency is recovering an overpayment.

[46 FR 47989, Sept. 30, 1981, as amended at 52 FR 43072, Nov. 9, 1987; 52 FR 48438, Dec. 22, 1987]

§ 436.116 Families terminated from AFDC because of increased earnings or hours of employment.

(a) If a family loses AFDC solely because of increased income from employment or increased hours of employment, the agency must continue to provide Medicaid for 4 months to all members of the family if—

(1) The family received AFDC in any 3 or more months during the 6-month period immediately before the month in which it became ineligible for AFDC; and

(2) At least one member of the family is employed throughout the 4-month period, although this need not be the same member for the whole period.

(b) The 4 calendar month period begins on the date AFDC is terminated. If AFDC benefits are terminated retroactively, the 4 calendar month period also begins retroactively with the first month in which AFDC was erroneously paid.

[43 FR 45218, Sept. 29, 1978, as amended at 45 FR 24837, Apr. 11, 1980]

§ 436.118 Children for whom adoption assistance or foster care maintenance payments are made.

The agency must provide Medicaid to children for whom adoption assistance or foster care maintenance payments are made under title IV-E of the Act.

[47 FR 28656, July 1, 1982]

§ 436.120 Qualified pregnant women and children.

(a) The Medicaid agency must provide Medicaid to a pregnant woman whose pregnancy has been medically verified and who—

(1) Would be eligible for an AFDC cash payment (or would be eligible for an AFDC cash payment if coverage under the State's AFDC plan included the AFDC-unemployed parents program) if her child had been born and was living with her in the month of payment;

(2) Is a member of a family that would be eligible for an AFDC cash payment if the State's AFDC plan included an AFDC-unemployed parents program; or

(3) Meets the income and resource requirements of the State's approved AFDC plan. In determining whether the woman meets the AFDC income and resource requirements, the unborn child or children are considered members of the household, and the woman's family is treated as though deprivation exists.

(b) The provisions of paragraphs (a) (1) and (2) of this section are effective October 1, 1984. The provisions of paragraph (a)(3) of this section are effective July 1, 1986.

(c) The agency must provide Medicaid to children who meet all of the following criteria:

(1) They are born after September 30, 1983 or, at State option, effective no earlier than April 1, 1986, an earlier designated date;

(2) They are under 5 years of age; and

(3) They meet the income and resource requirements of the State's approved AFDC plan.

[52 FR 43072, Nov. 9, 1987]

§ 436.124 Newborn children.

(a) The Medicaid agency must provide categorically needy Medicaid eligibility to a child born to a woman who is eligible for and receiving Medicaid on the date of the child's birth. The child is deemed to have applied and been found eligible for Medicaid on the date of birth and remains eligible as categorically needy for one year so long as the woman remains eligible and the child is a member of the woman's household. If the mother's basis of eligibility changes to medically needy, the child is eligible as medically needy under § 436.301(b)(1)(iii).

(b) The requirements under paragraph (a) of this section apply to children born on or after October 1, 1984.

[52 FR 43073, Nov. 9, 1987; 52 FR 48438, Dec. 22, 1987]

Subpart C—Options for Coverage as Categorically Needy

§ 436.200 Scope.

This subpart specifies options for coverage of individuals as categorically needy.

§ 436.201 Individuals included in optional groups.

Except where otherwise specified, an agency that chooses to cover an optional group must provide Medicaid to all eligible individuals in that group. For example, in the options applicable to families and children and the aged, blind, or disabled, the agency may not provide Medicaid only to families and children; similarly, in the options applicable to the aged, blind, or disabled, it may not cover only the blind.

OPTIONS FOR COVERAGE OF FAMILIES AND CHILDREN AND THE AGED, BLIND, AND DISABLED

§ 436.210 Individuals who would be eligible for but are not receiving cash assistance.

The agency may provide Medicaid to individuals who would be eligible for OAA, AFDC, AB, APTD, or AABD but who are not receiving these benefits.

§ 436.211 Individuals who would be eligible for cash assistance except for their institutional status.

The agency may provide Medicaid to individuals in title XIX reimbursable medical institutions and intermediate care facilities who are ineligible for OAA, AFDC, AB, APTD, or AABD because of lower income standards used under those programs to determine eligibility for institutionalized individuals, but who would be eligible for those programs if they were not institutionalized.

[45 FR 24887, Apr. 11, 1980]

§ 436.212 Individuals who would be eligible for cash assistance if the State plan for OAA, AFDC, AB, APTD, or AABD were as broad as allowed under the Act.

(a) The agency may provide Medicaid to individuals who—

(1) Would be eligible for OAA, AFDC, AB, APTD, or AABD if the State's plan under those programs included individuals whose coverage under title I, IV-A, X, XIV, or XVI is optional (for example, the agency may provide Medicaid to members of families with an unemployed parent even though the State's AFDC plan does not include them); or

(2) Would qualify for OAA, AFDC, AB, APTD, or AABD if the State's plan under those programs did not contain eligibility requirements more restrictive than, or in addition to, those required under the appropriate title of the Act. (For example, the agency may provide Medicaid to individuals who would meet the Federal definition of disability, 45 CFR 233.80, but who do not meet the State's more restrictive definitions.)

(b) The agency may cover one or more optional groups under any of the titles of the Act without covering all such groups.

[43 FR 45218, Sept. 29, 1978, as amended at 45 FR 24887, Apr. 11, 1980; 46 FR 47990, Sept. 30, 1981]

§ 436.217 Individuals receiving home and community-based services.

(a) The agency may provide Medicaid to any group or groups of individuals in the community who—

(1) Would be eligible for Medicaid if institutionalized;

(2) Would require institutionalization in the absence of home and community-based services under a waiver granted under Part 441, Subpart G, of this subchapter; and

(3) Receive the waivered services.

[50 FR 10026, Mar. 13, 1985]

OPTIONS FOR COVERAGE OF FAMILIES AND CHILDREN

§ 436.220 Individuals who would be eligible for AFDC if child care costs were paid from earnings.

(a) The agency may provide Medicaid to individuals who would be eligible for AFDC if their work-related child care costs were paid from their earnings rather than by a State agency as a service expenditure.

(b) The agency may use this option only if the State's AFDC plan deducts work-related child care costs from income to determine the amount of AFDC.

§ 436.222 Individuals under age 21 who would be eligible for AFDC but do not qualify as dependent children.

(a) The agency may provide Medicaid to individuals under age 21 (or, at State option, under age 20, 19 or 18) who would be eligible for AFDC if they met the definition of dependent child. (See 45 CFR 233.90(c)(1).)

(b) The agency may cover all individuals described in paragraph (a) of this section or reasonable classifications of those individuals. Examples of reasonable classifications are as follows:

(1) Individuals in foster homes or private institutions for whom a public agency is assuming a full or partial financial responsibility. If the agency covers these individuals, it may also provide Medicaid to individuals of the same age in foster homes or private institutions by private nonprofit agencies.

(2) Individuals in adoptions subsidized in full or in part by a public agency.

(3) Individuals in intermediate care facilities, if intermediate care facility services are provided under the plan. If the agency covers these individuals, it may also provide Medicaid to individuals in intermediate care facilities for the mentally retarded.

(4) Individuals receiving active treatment as inpatients in psychiatric facilities or programs, if inpatient psychiatric services for individuals under 21 are provided under the plan.

[46 FR 47990, Sept. 30, 1981]

OPTIONS FOR COVERAGE OF THE AGED, BLIND, AND DISABLED

§ 436.230 Essential spouses of aged, blind, or disabled individuals receiving cash assistance.

The agency may provide Medicaid to the spouse of an individual receiving OAA, AB, APTD, or AABD, if—

(a) The spouse is living with the individual receiving cash assistance;

(b) The cash assistance agency has determined that the spouse is essential to the well-being of the individual and has considered the spouse's needs in determining the amount of cash assistance provided to the individual.

Subpart D—Optional Coverage of the Medically Needy

§ 436.300 Scope.

This subpart specifies the option for coverage of medically needy individuals.

§ 436.301 General rules.

(a) A Medicaid agency may provide Medicaid to individuals specified in this subpart who—

(1) Either—

(i) Have income that meets the standards in § 436.814; or

(ii) If their income is more than allowed under those standards, have incurred medical expenses at least equal to the difference between their income and the applicable income standards; and

(2) Have resources that meet the standards in § 436.843.

(b) If the agency chooses this option, the following provisions apply:

(1) The agency must provide Medicaid to the following individuals who meet the requirements of paragraph (a) of this section:

(i) All pregnant women during the course of their pregnancy who, except for income and resources, would be eligible for Medicaid as mandatory or optional categorically needy under subparts B and C of this part;

(ii) All individuals under 18 years of age who, except for income and resources, would be eligible for Medicaid as mandatory categorically needy under subpart B of this part;

(iii) All newborn children born on or after October 1, 1984, to a woman who is eligible as medically needy and receiving Medicaid on the date of the child's birth. The child is deemed to have applied and been found eligible for Medicaid on the date of birth and remains eligible as medically needy for one year so long as the woman remains eligible and the child is a member of the woman's household. If the woman's basis of eligibility changes to categorically needy, the child is eligible as categorically needy under § 436.124. The woman is considered to remain eligible if she meets the spend-down requirements in any consecutive budget period following the birth of the child.

(2) The agency may provide Medicaid to any or all of the following groups of individuals:

(i) Individuals under age 21 (§ 436.308).

(ii) Caretaker relatives (§ 436.310).

(iii) Aged (§ 436.320).

(iv) Blind (§ 436.321).

(v) Disabled (§ 436.322).

(3) If the agency provides Medicaid to any individual in a group specified in paragraph (b)(2) of this section, the agency must provide Medicaid to all individuals eligible to be members of that group.

[46 FR 47990, Sept. 30, 1981; 46 FR 54743, Nov. 4, 1981, as amended at 52 FR 43073, Nov. 9, 1987]

§ 436.308 Medically needy coverage of individuals under age 21.

(a) If the agency provides Medicaid to the medically needy, it must provide Medicaid to individuals under age 21 (or, at State option, under age 20, 19, or 18), as specified in paragraph (b) of this section, who meet the income and resource standards in Subpart I of this part. (See § 436.301 for required coverage as either categorically or medically needy.)

(b) The agency may cover all individuals in paragraph (a) of this section or individuals in reasonable classifications. Examples of reasonable classifications are as follows:

(1) Individuals in foster homes or private institutions for whom a public agency is assuming a full or partial financial responsibility. If the agency covers these individuals, it may also provide Medicaid to individuals placed in foster homes or private institutions by private nonprofit agencies.

(2) Individuals in adoptions subsidized in full or in part by a public agency

(3) Individuals in intermediate care facilities, if intermediate care facility services are provided under the plan. If the agency covers these individuals, it may also provide Medicaid to individuals in intermediate care facilities for the mentally retarded.

(4) Individuals receiving active treatment as inpatients in psychiatric facilities or programs, if inpatient psychiatric services for individuals under 21 are provided under the plan.

[46 FR 47990, Sept. 30, 1981]

§ 436.310 Medically needy coverage of caretaker relatives.

(a) If the agency provides for the medically needy, it may provide Medicaid to caretaker relatives, as specified in paragraph (b) of this section, who meet the income and resource standards of Subpart I of this part.

(b) "Caretaker relatives" mean individuals who—

(1) Meet the definition of a caretaker relative under 45 CFR 233.90(c)(1)(v)(A); and

(2) Have in their care an individual who is determined to be dependent, as specified in § 436.510.

[46 FR 47990, Sept. 30, 1981]

§ 436.320 Medically needy coverage of the aged.

If the agency provides Medicaid to the medically needy, it may provide Medicaid to individuals who—

(a) Are 65 years of age and older, as provided for in § 436.520; and

(b) Meet the income and resource requirements of Subpart I of this part.

[46 FR 47991, Sept. 30, 1981]

§ 436.321 Medically needy coverage of the blind.

If the agency provides Medicaid to the medically needy, it may provide Medicaid to blind individuals who meet—

(a) The requirements for blindness, as specified in §§ 436.530 and 436.531; and

(b) The income and resource requirements of Subpart I of this part.

[46 FR 47991, Sept. 30, 1981]

§ 436.322 Medically needy coverage of the disabled.

If the agency provides Medicaid to the medically needy, it may provide

Medicaid to disabled individuals who meet—

(a) The requirements for disability, as specified in §§ 436.540 and 436.541; and

(b) The income and resource requirements of Subpart I of this part.

[46 FR 47991, Sept. 30, 1981]

Subpart E—General Eligibility Requirements

§ 436.400 Scope.

This subpart prescribes general requirements for determining the eligibility of both categorically needy and medically needy individuals specified in Subparts B, C, and D of the part.

§ 436.401 General rules.

(a) The agency may not impose any eligibility requirement that is prohibited under title XIX.

(b) The agency must base any optional group covered under Subparts B and C of this part on reasonable classifications that do not result in arbitrary or inequitable treatment of individuals and groups and are consistent with the objectives of title XIX.

(c) The agency must not use requirements for determining eligibility for optional coverage groups that are more restrictive than those used under the State plans for OAA, AFDC, AB, APTD or AABD.

§ 436.402 Citizenship and alienage.

The agency must provide Medicaid to otherwise eligible residents of the United States who are—

(a) Citizens; or

(b) Aliens lawfully admitted for permanent residence or permanently residing in the United States under color of law, including any alien who is lawfully present in the United States under section 203(a)(7) or section 212(d)(5) of the Immigration and Nationality Act.

§ 436.403 State residence.

(a) *Requirement.* The agency must provide Medicaid to eligible residents of the State, including residents who are absent from the State. The conditions under which payment for service is provided to out-of-State residents are set forth in § 431.52 of this chapter.

(b) *Definition.* For purposes of this section—"Institution" has the same meaning as "Institution" and "Medical institution", as defined in § 435.1009 of this chapter. For purposes of State placement, the term also includes "foster care homes", licensed as set forth in 45 CFR 1355.20, and providing food, shelter and supportive services to one or more persons unrelated to the proprietor.

(c) *Incapability of indicating intent.* For purposes of this section, an individual is considered incapable of indicating intent if the individual—

(1) Has an I.Q. of 49 or less or has a mental age of 7 or less, based on tests acceptable to the mental retardation agency in the State;

(2) Is judged legally incompetent; or

(3) Is found incapable of indicating intent based on medical documentation obtained from a physician, psychologist, or other person licensed by the State in the field of mental retardation.

(d) *Who is a State resident.* A resident of a State is any individual who:

(1) Meets the conditions in paragraphs (e) through (h) of this section; or

(2) Meets the criteria specified in an interstate agreement under paragraph (j) of this section.

(e) *Placement by a State in an out-of-state institution*—(1) *General rule.* Any agency of the State, including an entity recognized under State law as being under contract with the State for such purposes, that arranges for an individual to be placed in an institution located in another State, is recognized as acting on behalf of the State in making a placement. The State arranging or actually making the placement is considered as the individual's State of residence.

(2) Any action beyond providing information to the individual and the individual's family would constitute arranging or making a State placement. However, the following actions do not constitute State placement:

(i) Providing basic information to individuals about another State's Medicaid program, and information about the availability of health care services and facilities in another State.

(ii) Assisting an individual in locating an institution in another State provided the individual is capable of indicating intent and independently decides to move.

(3) When a competent individual leaves the facility in which the individual is placed by a State, that individual's State of residency for Medicaid purposes is the State where the individual is physically located.

(4) Where placement is initiated by a State because the State lacks a sufficient number of appropriate facilities to provide services to its residents, the State making the placement is the individual's State of residence for Medicaid purposes.

(f) *Individuals receiving title IV-E payments.* For individuals of any age who are receiving Federal payment for foster care and adoption assistance under title IV-E of the Social Security Act, the State of residence is the State making the payment.

(g) *Individuals under age 21.* (1) For any individual who is emancipated from his or her parents or who is married and capable of indicating intent, the State of residence is the State where the individual is living with the intention to remain there permanently or for an indefinite period.

(2) For any individual not residing in an institution as defined in paragraph (b) whose Medicaid eligibility is based on blindness or disability, the State of residence is the State in which the individual is living.

(3) For any other non-institutionalized individual not subject to paragraph (h)(1) or (h)(2) of this section, the State of residence is determined in accordance with 45 CFR 233.40, the rules governing residence under the AFDC program.

(4) For any institutionalized individual who is neither married nor emancipated, the State of residence is—

(i) The parents' or legal guardian's current State of residence at the time of placement; or

(ii) The current State of residence of the parent or legal guardian who files the application, if the individual is institutionalized in that State. If a legal guardian has been appointed and the parental rights are terminated, the State of residence of the guardian is used instead of the parent's.

(iii) The State of residence of the individual or party who files an application is used if the individual has been abandoned by his or her parent(s), does not have a legal guardian and is institutionalized in that State.

(h) *Individuals age 21 and over.* (1) For any individual not residing in an institution as defined in paragraph (b), the State of residence is the State where the individual is—

(i) Living with the intention to remain there permanently or for an indefinite period (or if incapable of stating intent, where the individual is living); or

(ii) Living and which the individual entered with a job commitment or seeking employment (whether or not currently employed).

(2) For any institutionalized individual who became incapable of indicating intent before age 21, the State of residence is—

(i) That of the parents applying for Medicaid on the individual's behalf, if the parents reside in separate States;

(ii) The parent's or legal guardian's State of residence at the time of placement; or

(iii) The current State of residence of the parent or legal guardian who files the application, if the individual is institutionalized in that State. If a legal guardian has been appointed and parental rights are terminated, the State of residence of the guardian is used instead of the legal parent's.

(iv) The State of residence of the individual or party who files an application is used if the individual has been abandoned by his or her parent(s), does not have a legal guardian and is institutionalized in that State.

(3) For any institutionalized individual who became incapable of indicating intent at or after age 21, the State of residence is the State in which the individual is physically present, except where another State makes a placement.

(4) For any other institutionalized individual, the State of residence is the State where the individual is living with the intention to remain there

permanently or for an indefinite period.

(i) *Specific prohibitions.* (1) The agency may not deny Medicaid eligibility because an individual has not resided in the State for a specified period.

(2) The agency may not deny Medicaid eligibility to an individual in an institution, who satisfies the residency rules set forth in this section, on the grounds that the individual did not establish residence in the State before entering the institution.

(3) The agency may not deny or terminate a resident's Medicaid eligibility because of that person's temporary absence from the State if the person intends to return when the purpose of the absence has been accomplished, unless another State has determined that the person is a resident there for purposes of Medicaid.

(j) *Interstate agreements.* A State may have a written agreement with another State setting forth rules and procedures resolving cases of disputed residency. These agreements may establish criteria other than those specified in paragraphs (c) through (h) of this section, but must not include criteria that result in loss of residency in both States or that are prohibited by paragraph (i) of this section. The agreements must contain a procedure for providing Medicaid to individuals pending resolution of the case.

States may use interstate agreements for purposes other than cases of disputed residency to facilitate administration of the program, and to facilitate the placement and adoption of title IV-E individuals when the child and his or her adoptive parent(s) move into another State.

(k) *Continued Medicaid for institutionalized recipients.* An agency is providing Medicaid to an institutionalized recipient who, as a result of this section, would be considered a resident of a different State—

(1) The agency must continue to provide Medicaid to that recipient from June 24, 1983 until July 5, 1984 unless it makes arrangements with another State of residence to provide Medicaid at an earlier date; and

(2) Those arrangements must not include provisions prohibited by paragraph (g) of this section.

(l) *Cases of disputed residency.* Where two or more States cannot resolve which State is the State of residence, the State where the individual is physically located is the State of residence.

[49 FR 13533, Apr. 5, 1984]

§ 436.404 Applicant's choice of category.

The agency must allow an individual who would be eligible under more than one category to have his eligibility determined for the category he selects.

Subpart F—Categorical Requirements for Medicaid Eligibility

§ 436.500 Scope.

This subpart prescribes categorical requirements for determining the eligibility of both categorically needy and medically needy individuals specified in Subparts B, C, and D of this part.

DEPENDENCY

§ 436.510 Determination of dependency.

For families with dependent children who are not receiving AFDC, the agency must use the definitions and procedures used under the State's AFDC plan to determine whether—

(a) An individual under age 21 is a dependent child because he is deprived of parental support or care; and

(b) An individual is an eligible member of a family with dependent children.

AGE

§ 436.520 Age requirements for the aged and children.

(a) The agency must not impose—

(1) An age requirement of more than 65 years;

(2) An age requirement that excludes an individual under age 19 who meets the definition of dependent child under the State title IV-A plan; or

(3) A lower age requirement than that under the State AFDC plan.

(b) In determining age, the agency must use the common law method (under which an age is reached the day before the anniversary of birth) or the popular usage method (under which a specific age is reached on the anniversary of birth), whichever is used under the corresponding State plan for OAA, AFDC, AB, APTD, or AABD.

(c) The agency may use an arbitrary date, such as July 1, for determining an individual's age if the year, but not the month, of his birth is known.

[43 FR 45204, Sept. 29, 1978, as amended at 46 FR 47991, Sept. 30, 1981]

BLINDNESS

§ 436.530 Definition of blindness.

(a) *Definition.* The agency must use the definition of blindness that is used in the State plan for AB or AABD.

(b) *State plan requirement.* The State plan must contain the definition of blindness, expressed in ophthalmic measurements.

§ 436.531 Determination of blindness.

In determining blindness—

(a) A physician skilled in the diseases of the eye or an optometrist, whichever the individual selects, must examine him, unless both of the applicant's eyes are missing;

(b) The examiner must submit a report of examination to the Medicaid agency; and

(c) A physician skilled in the diseases of the eye (for example, an ophthalmologist or an eye, ear, nose, and throat specialist) must review the report and determine on behalf of the agency—

(1) Whether the individual meets the definition of blindness; and

(2) Whether and when reexaminations are necessary for periodic redeterminations of eligibility, as required under § 435.916 of this subchapter. Blindness is considered to continue until the reviewing physician determines that the recipient's vision no longer meets the definition.

[43 FR 45218, Sept. 29, 1978, as amended at 44 FR 17939, Mar. 23, 1979]

DISABILITY

§ 436.540 Definition of disability.

(a) *Definition.* The agency must use the definition of permanent and total disability that is used in the State plan for APTD or AABD. (See 45 CFR 233.80(a)(1) for the Federal recommended definition of permanent and total disability.)

(b) *State plan requirement.* The State plan must contain the definition of permanent and total disability.

§ 436.541 Determination of disability.

(a) The agency must obtain a medical report and a social history for individuals applying for Medicaid on the basis of disability. The medical report must include a diagnosis based on medical evidence. The social history must contain enough information to enable the agency to determine disability.

(b) A physician and social worker, qualified by professional training and experience, must review the medical report and social history and determine on behalf of the agency whether the individual meets the definition of disability. The physician must determine whether and when reexaminations will be necessary for periodic redeterminations of eligibility as required under § 435.916 of this subchapter.

(c) In subsequently determining disability, the physician and social worker must review reexamination reports and the social history and determine whether the individual continues to meet the definition. Disability is considered to continue until this determination is made.

[43 FR 45218, Sept. 29, 1978, as amended at 44 FR 17939, Mar. 23, 1979]

Subpart G—General Financial Eligibility Requirements and Options

§ 436.600 Scope.

This subpart prescribes general financial requirements and options for determining the eligibility of both categorically needy and medically needy individuals specified in Subparts B, C, and D of this part. Subparts H and I prescribe additional financial requirements.

[45 FR 8986, Feb. 11, 1980]

§ 436.602 Limitation on the financial responsibility of relatives.

(a) Except for a spouse of an individual or a parent for a child who is under 21 or blind or disabled, the agency must not—

(1) Consider income and resources of any relative available to an individual; nor

(2) Collect reimbursement from any relative for amounts paid by the agency for services provided to an individual.

(b) The income and resources of spouses and parents must be considered in determining financial eligibility as provided for the categorically needy in Subpart H and the medically needy in Subpart I.

[45 FR 82259, Dec. 15, 1980]

§ 436.603 Applications for other benefits.

(a) As a condition of eligibility, the agency must require applicants and recipients to take all necessary steps to obtain any annuities, pensions, and retirement and disability benefits to which they are entitled, unless they can show good cause for not doing so.

(b) Annuities, pensions, and retirement and disability benefits include, but are not limited to, veterans' compensation and pensions, OASDI benefits, railroad retirement benefits, and unemployment compensation.

§ 436.604 Assignment of rights to benefits.

For medical assistance furnished on or after October 1, 1984—

(a) As a condition of eligibility, the agency must require legally able applicants and recipients to assign rights to medical support and other third party payments to the Medicaid agency and to cooperate with the agency in obtaining medical support or payments. (Part 433, Subpart D, contains specific requirements for these assignments.)

(b) The requirements for assignment of rights must be applied uniformly for all groups covered under the plan.

[50 FR 46666, Nov. 12, 1985]

Subpart H—Financial Requirements for the Categorically Needy

§ 436.700 Scope.

This subpart prescribes financial requirements for determining the eligibility of categorically needy individuals under Subparts B and C of this part. The requirements apply only to individuals who are not receiving cash assistance under OAA, AFDC, AB, APTD, or AABD. The financial eligibility requirements of the cash assistance programs apply to those individuals who are receiving cash assistance.

§ 436.711 Determination of financial eligibility.

In determining eligibility of individuals specified in Subparts B and C of this part who are not recipients of cash assistance, the agency must apply the financial eligibility requirements of the State plan for OAA, AFDC, AB, APTD, or AABD that would be used if the individual were applying for cash assistance. This includes requirements on financial responsibility of spouses and parents, except that in determining eligibility of families and children, the agency must consider parental income and resources as available to a child who is living with the parents until he becomes 21, even if State law confers adult status below age 21.

[48 FR 39629, Sept. 1, 1983]

Subpart I—Financial Requirements for the Medically Needy

§ 436.800 Scope.

This subpart prescribes financial requirements for determining the eligibility of medically needy individuals under Subpart D of this part.

MEDICALLY NEEDY INCOME STANDARDS

§ 436.811 Medically needy income standards: General requirements.

To determine eligibility of medically needy individuals, the agency must use an income standard under this subpart that is—

(a) Based on family size;

(b) Uniform for all individuals in a covered group; and

(c) Reasonable (See § 436.812).

[46 FR 54744, Nov. 4, 1981]

§ 436.812 Medically needy income standards: Reasonableness.

(a) The agency must use a medically needy income standard that is reasonable, according to the provisions of this section.

(b) The following medically needy income standards are presumed to be reasonable:

(1) The agency provides for one medically needy income standard for all covered medically needy groups. Except as provided in paragraph (c) of this section, that standard must at least equal the highest income standard used on or after January 1, 1966, to determine eligibility for the OAA, AFDC, AB, APTD, and AABD programs that are related to the covered medically needy groups.

(2) The agency provides for a different medically needy income standard for each covered medically needy group. Except as provided in paragraph (c) of this section, the standard for each covered group must at least equal the income standard used on or after January 1, 1966, to determine eligibility for the OAA, AFDC, AB, APTD, or AABD program that is related to that covered medically needy group.

(c) The agency may use a medically needy income standard, that is lower than the standards specified in paragraph (b) of this section, if the lower income standard at least equals the maximum amount allowed for purposes of FFP.

(d) If the agency provides for a medically needy income standard not specified in paragraphs (b) or (c) of this section—

(1) That standard is not presumed to be reasonable; and

(2) HCFA must approve that standard.

[46 FR 47991, Sept. 30, 1981; 46 FR 54744, Nov. 4, 1981]

§ 436.814 Medically needy income standard: State plan requirements.

(a) The State plan must specify the income standard for each covered medically needy group.

(b) If the agency provides for an income standard that is not presumed to be reasonable under § 435.812, the State plan must describe that standard.

[46 FR 47991, Sept. 30, 1981]

FINANCIAL RESPONSIBILITY OF RELATIVES

§ 436.821 Financial responsibility of spouses and parents.

In determining eligibility of medically needy individuals, the agency may use the rules for determining whether the income of a spouse or parent is available to the individual that would be used if he were applying for OAA, AFDC, AB, APTD or AABD. However:

(a) For individuals under age 21 and caretaker relatives, the agency must consider parental income and resources available to a child who is living with the parent until he becomes 21, even if State law confers adult status below age 21; and

(b) When either an individual or his or her aged, blind, or disabled spouse is institutionalized, the agency may consider the income of an individual as available to an aged, blind, or disabled spouse under the procedure set forth in either paragraph (b)(1), (b)(2), or (b)(3) of this section:

(1) The agency may use the SSI criteria for determining the amount and duration of availability of income (see § 435.723);

(2) The agency may use criteria more liberal than those SSI criteria; or

(3) The agency may consider only income actually contributed when the spouses have ceased to live together.

[45 FR 82259, Dec. 15, 1980, as amended at 46 FR 47991, Sept. 30, 1981]

MEDICALLY NEEDY INCOME ELIGIBILITY AND LIABILITY FOR PAYMENT OF MEDICAL EXPENSES

§ 436.831 Income eligibility.

The agency must determine income eligibility of medically needy individuals in accordance with this section. The agency must use a prospective period of not more than 6 months to compute income.

(a) *Determining countable income.* The agency must, to determine countable income, deduct amounts that would be deducted in determining eligibility under the State's approved plan for OAA, AFDC, AB, APTD, or AABD.

(b) *Eligibility based on countable income.* If countable income determined under paragraph (a) of this section is equal to or less than the applicable income standard under § 436.814, the individual is eligible for Medicaid.

(c) *Deduction of incurred medical expenses: Order of deduction.* (1) If countable income exceeds the income standard, the agency must deduct from income, in the following order, incurred medical expenses that are not subject to payment by a third party:

(i) Medicare and other health insurance premiums, deductibles, or coinsurance charges incurred by the individual or family or financially responsible relatives, including enrollment fees, copayments, or deductibles imposed under § 447.51 or §447.53 of this subchapter.

(ii) Expenses incurred by the individual or family or financially responsible relatives for necessary medical and remedial services that are recognized under State law but not included in the plan.

(iii) Expenses incurred by the individual or family or by financially responsible relatives for necessary medical and remedial services that are included in the plan.

(2) The agency may set reasonable limits on the amounts of incurred medical expenses to be deducted from income under paragraphs (c)(1)(i) and (ii) of this section.

(d) *Eligibility based on incurred medical expenses.* Once deduction of incurred medical expenses reduces income to the income standard, the individual is eligible for Medicaid.

[43 FR 45218, Sept. 29, 1978, as amended at 45 FR 24887, Apr. 11, 1980; 46 FR 47991, Sept. 30, 1981]

§ 436.832 Post-eligibility treatment of income and resources of institutionalized individuals: Application of patient income to the cost of care.

(a) *Application of patient income.* The agency must reduce its payment to an institution, for services provided to an individual specified in paragraph (b) of this section, by the amount that remains after deducting the amounts specified in paragraphs (c) and (d) from the individual's total income, as determined in paragraph (e) of this section.

(b) *Applicability.* This section applies to medically needy individuals in medical institutions and intermediate care facilities.

(c) *Required deductions.* The agency must deduct the following amounts, in the following order, from the individual's total income as determined under paragraph (e) of this section. Income that was disregarded in determining eligibility must be considered in this process.

(1) A personal needs allowance that is reasonable in amount for clothing and other personal needs of the individual while in the institution.

(2) For an individual with only a spouse at home, an additional amount for the maintenance needs of the spouse. This amount must be based on a reasonable assessment of need but must not exceed the higher of—

(i) The amount of the highest need standard for an individual without income and resources under the State's approved plan for OAA, AFDC, AB, APTD, or AABD; or

(ii) The amount of the highest medically needy income standard for one person established under § 436.814.

(3) For an individual with a family at home, an additional amount for the maintenance needs of the family. This amount must—

(i) Be based on a reasonable assessment of their financial need;

(ii) Be adjusted for the number of family members living in the home; and

(iii) Not exceed the highest of the following need standards for a family of the same size:

(A) The standard used to determine eligibility under the State's Medicaid plan, as provided for in § 436.814.

(B) The standard used to determine eligibility under the State's approved AFDC plan.

(4) Amounts for Medicare and other health insurance premiums, deductibles, or coinsurance charges that are

not subject to payment by a third party.

(d) *Optional deductions.* In determining the amount of the individual's income to be used to reduce the agency's payment to the institution, the agency may deduct the following amounts from the individual's total income as determined under paragraph (e) of this section:

(1) Necessary medical or remedial services included in the State's Medicaid plan for the medically needy, which exceed limitations on amount, duration or scope imposed by the agency, subject to reasonable limits the agency may establish on amounts of these expenses;

(2) Necessary medical or remedial care recognized under State law but not covered under the State's Medicaid plan, subject to reasonable limits the agency may establish on amounts of these expenses; and

(3) For single individuals and couples, an amount (in addition to the personal needs allowance) for maintenance of the individual's or couple's home if—

(i) The amount is deducted for not more than a 6-month period; and

(ii) A physician has certified that either of the individuals is likely to return to the home within that period.

(e) *Determination of income*—(1) *Option.* In determining the amount of an individual's income to be used to reduce the agency's payment to the institution, the agency may use total income received or it may project total monthly income for a prospective period not to exceed 6 months.

(2) *Basis for projection.* The agency must base the projection on income received in the preceding period, not to exceed 6 months, and on income expected to be received.

(3) *Adjustments.* At the end of the prospective period specified in paragraph (e)(1) of this section, or when any significant change occurs, the agency must reconcile estimates with income received.

(f) *Determination of medical expenses*—(1) *Option.* In determining the amount of medical expenses to be deducted from an individual's income, the agency may deduct incurred medical expenses, or it may project medical expenses for a prospective period not to exceed 6 months.

(2) *Basis for projection.* The agency must base the estimate on medical expenses incurred in the preceding period, not to exceed 6 months, and medical expenses expected to be incurred.

(3) *Adjustments.* At the end of the prospective period specified in paragraph (f)(1) of this section, or when any significant change occurs, the agency must reconcile estimates with incurred medical expenses.

[45 FR 24888, Apr. 11, 1980, as amended at 46 FR 47991, Sept. 30, 1981; 48 FR 5735, Feb. 8, 1983; 53 FR 3597, Feb. 8, 1988]

MEDICALLY NEEDY RESOURCE STANDARDS

§ 436.840 Medically needy resource standards: General requirements.

To determine eligibility of medically needy individuals, the Medicaid agency must use a resource standard under this subpart that is—

(a) Based on family size;

(b) Uniform for all individuals in a group; and

(c) Reasonable (See § 436.841).

[46 FR 47992, Sept. 30, 1981; 46 FR 54744, Nov. 4, 1981]

§ 436.841 Medically needy resource standards: Reasonableness.

(a) The agency must use a medically needy resource standard that is reasonable, according to the provisions of this section.

(b) The following medically needy resource standards are presumed to be reasonable:

(1) The agency provides one medically needy resource standard for all covered medically needy groups. The standard must at least equal the highest resource standard used on or after January 1, 1966, to determine eligibility for the OAA, AFDC, AB, APTD, and AABD programs that are related to the covered medically needy groups.

(2) The agency provides for a different medically needy resource standard for each covered medically needy group. The standard for each covered group must at least equal the highest resource standard used on or after January 1, 1966, to determine eligibil-

ity for the OAA, AFDC, AB, APTD, or AABD program that is related to that covered medically needy group.

(c) If the agency provides for a medically needy resource standard not specified in paragraph (b) of this section—

(1) That standard is not presumed to be reasonable; and

(2) HCFA must approve the standard.

[46 FR 47992, Sept. 30, 1981; 46 FR 54744, Nov. 4, 1981]

§ 436.843 Medically needy resource standards: State plan requirements.

(a) The State plan must specify the resource standard for each covered medically needy group.

(b) If the agency provides for a resource standard that is not presumed reasonable under § 436.841, the State plan must describe that standard.

[46 FR 47992, Sept. 30, 1981; 46 FR 54744, Nov. 4, 1981]

DETERMINING ELIGIBILITY ON THE BASIS OF RESOURCES

§ 436.845 Medically needy resource eligibility.

To determine eligibility on the basis of resources for medically needy individuals, the agency must—

(a) Consider only the individual's resources and those that are considered available to him under the financial responsibility requirements for relatives under § 436.821;

(b) Consider only resources available during the period for which income is computed under § 436.831(a);

(c) Deduct the value of resources that would be deducted in determining eligibility under the State's plan for OAA, AFDC, AB, APTD, or AABD; and

(d) Apply the resource standards established under § 436.843.

[43 FR 45218, Sept. 29, 1978, as amended at 46 FR 47992, Sept. 30, 1981]

TREATMENT OF INCOME AND RESOURCES

§ 436.850 Treatment of income and resources: General requirements.

To determine eligibility of medically needy individuals, a Medicaid agency must use a methodology for the treatment of income and resources that is—

(a) Uniform for all individuals in a covered group; and

(b) Reasonable (see § 436.851).

[46 FR 47992, Sept. 30, 1981]

§ 436.851 Treatment of income and resources: Reasonableness.

(a) The agency must use a methodology for the treatment of income and resources, to determine eligibility of the medically needy, that is reasonable.

(b) The methodology used to determine eligibility of cash assistance program related to the covered medically needy group is presumed to be reasonable.

(c) If the agency uses a methodology not described in paragraph (b) of this section—

(1) The methodology is not presumed to be reasonable; and

(2) HCFA must approve that methodology.

[46 FR 47992, Sept. 30, 1981]

§ 436.852 Treatment of income and resources: State plan requirements.

(a) The State plan must specify the methodology used to treat the income and resources for each covered medically needy group.

(b) If the agency uses a methodology that is not presumed to be reasonable under § 436.851, the State plan must describe that methodology.

[46 FR 47992, Sept. 30, 1981]

Subpart J—Eligibility in Guam, Puerto Rico, and the Virgin Islands

SOURCE: 44 FR 17939, Mar. 23, 1979, unless otherwise noted.

§ 436.900 Scope.

This subpart sets forth requirements for processing applications, determining eligibility, and furnishing Medicaid.

§ 436.901 General requirements.

The Medicaid agency must comply with all the requirements of Part 435, Subpart J, of this subchapter, except those specified in § 435.909.

§ 436.909 Automatic entitlement to Medicaid following a determination of eligibility under other programs.

The agency may not require a separate application for Medicaid from an individual if the individual receives cash assistance under a State plan for OAA, AFDC, AB, APTD, or AABD.

Subpart K—Federal Financial Participation (FFP)

§ 436.1000 Scope.

This subpart specifies when, and the extent to which, FFP is available in expenditures for determining eligibility and for Medicaid services to individuals determined eligible under this part, and prescribes limitations and conditions on FFP for those expenditures.

FFP FOR EXPENDITURES FOR DETERMINING ELIGIBILITY AND PROVIDING SERVICES

§ 436.1001 FFP for administration.

(a) FFP is available in the necessary administrative costs the State incurs in determining and redetermining Medicaid eligibility and in providing Medicaid to eligible individuals.

(b) Administrative costs include any costs incident to an eye examination or medical examination to determine whether an individual is blind or disabled.

§ 436.1002 FFP for services.

(a) FFP is available in expenditures for Medicaid services for all recipients whose coverage is required or allowed under this part.

(b) FFP is available in expenditures for services provided to recipients who were eligible for Medicaid in the month in which the medical care or services were provided, except that, for recipients who establish eligibility for Medicaid by deducting incurred medical expenses from income, FFP is not available for expenses that are the recipient's liability.

[43 FR 45218, Sept. 29, 1978, as amended at 44 FR 17940, Mar. 23, 1979]

§ 436.1003 Recipients overcoming certain conditions of eligibility.

FFP is available for a temporary period specified in the State plan in expenditures for services provided to recipients who are overcoming certain eligibility conditions, including blindness, disability, continued absence or incapacity of a parent, or unemployment of a parent.

[45 FR 24888, Apr. 11, 1980]

§ 436.1004 Institutionalized individuals.

(a) FFP is not available in expenditures for services provided to—

(1) Individuals who are inmates of public institutions as defined in § 435.1009; or

(2) Individuals under age 65 who are patients in an institution for mental diseases unless they are under age 22 and are receiving inpatient psychiatric services under § 440.160 of this subchapter.

(b) The exclusion of FFP described in paragraph (a) of this section does not apply during that part of the month in which the individual is not an inmate of a public institution or a patient in an institution for mental diseases.

(c) An individual on conditional release or convalescent leave from an institution for mental diseases is not considered to be a patient in that institution. However, such an individual who is under age 22 and has been receiving inpatient pyschiatric services under § 440.160 of this subchapter is considered to be a patient in the institution until he is unconditionally released or, if earlier, the date he reaches age 22.

[43 FR 45204, Sept. 29, 1978, as amended at 50 FR 13200, Apr. 3, 1985; 50 FR 38811, Sept. 25, 1985]

§ 436.1005 Definitions relating to institutional status.

For purposes of FFP, the definitions in § 435.1009 of this subchapter apply to this part.

PART 440—SERVICES: GENERAL PROVISIONS

Subpart A—Definitions

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440.200 Basis, purpose, and scope.
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440.240 Comparability of services for groups.
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440.260 Methods and standards to assure quality of services.
440.270 Religious objections.

AUTHORITY: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

SOURCE: 43 FR 45224, Sept. 29, 1978, unless otherwise noted.

Subpart A—Definitions

§ 440.1 Basis and purpose.

This subpart interprets section 1905(a) of the Act, which lists the services included in the term "medical assistance," sections 1905 (c), (d), (f)-(i), (l), and (m), which define some of those services, and section 1915(c), which lists as "medical assistance" certain home and community-based services provided under waivers under that section to individuals who would otherwise require institutionalization. It also implements sec. 1902(a)(43) with respect to laboratory services (see also §§ 447.10 and 447.342 for related provisions on laboratory services), and implements section 1913 of the Act with respect to "swing-bed" services (see related provisions in §§ 447.280 and 482.66 of this chapter).

[47 FR 31532, July 20, 1982, as amended at 51 FR 22041, June 17, 1986]

§ 440.2 Specific definitions; definitions of services for FFP purposes.

(a) *Specific definitions.*

Inpatient means a patient who has been admitted to a medical institution as an inpatient on recommendation of a physician or dentist and who—

(1) Receives room, board and professional services in the institution for a 24 hour period or longer, or

(2) Is expected by the institution to receive room, board and professional services in the institution for a 24 hour period or longer even though it later develops that the patient dies, is discharged or is transferred to another facility and does not actually stay in the institution for 24 hours.

Outpatient means a patient of an organized medical facility, or distinct part of that facility who is expected by the facility to receive and who does receive professional services for less than a 24-hour period regardless of the hour of admission, whether or not a bed is used, or whether or not the patient remains in the facility past midnight.

Patient means an individual who is receiving needed professional services that are directed by a licensed practitioner of the healing arts toward the maintenance, improvement, or protection of health, or lessening of illness, disability, or pain. (See also § 435.1009 of this subchapter for definitions relating to institutional care.)

(b) *Definitions of services for FFP purposes.* Except as limited in Part 441, FFP is available in expenditures under the State plan for medical or remedial care and services as defined in this subpart.

[43 FR 45224, Sept. 29, 1978, as amended at 52 FR 47934, Dec. 17, 1987]

§ 440.10 Inpatient hospital services, other than services in an institution for mental diseases.

(a) *Inpatient hospital services* means services that—

(1) Are ordinarily furnished in a hospital for the care and treatment of inpatients;

(2) Except in the case of nurse-midwife services, as specified in § 440.165, are furnished under the direction of a physician or dentist; and

(3) Are furnished in an institution that—

(i) Is maintained primarily for the care and treatment of patients with disorders other than mental diseases;

(ii) Is licensed or formally approved as a hospital by an officially designated authority for State standard-setting;

(iii) Except in the case of medical supervision of nurse-midwife services, as specified in § 440.165, meets the requirements for participation in Medicare as a hospital; and

(iv) Has in effect a utilization review plan, applicable to all Medicaid patients, that meets the requirements of § 482.30 of this chapter, unless a waiver has been granted by the Secretary.

(b) Inpatient hospital services do not include SNF and ICF services furnished by a hospital with a swing-bed approval.

[47 FR 21050, May 17, 1982, as amended at 47 FR 31532, July 20, 1982; 51 FR 22041, June 17, 1986, 52 FR 47934, Dec. 17, 1987]

§ 440.20 Outpatient hospital services and rural health clinic services.

(a) *Outpatient hospital services* means preventive, diagnostic, therapeutic, rehabilitative, or palliative services that—

(1) Are furnished to outpatients;

(2) Except in the case of nurse-midwife services, as specified in § 440.165, are furnished by or under the direction of a physician or dentist; and

(3) Are furnished by an institution that—

(i) Is licensed or formally approved as a hospital by an officially designated authority for State standard-setting; and

(ii) Except in the case of medical supervision of nurse-midwife services, as specified in § 440.165, meets the requirements for participation in Medicare as a hospital; and

(4) May be limited by a Medicaid agency in the following manner: A Medicaid agency may exclude from the definition of "outpatient hospital services" those types of items and services that are not generally furnished by most hospitals in the State.

(b) *Rural health clinic services.* If nurse practitioners or physician assistants (as defined in § 481.1 of this chapter) are not prohibited by State law from furnishing primary health care, "rural health clinic services" means the following services when furnished by a rural health clinic that has been certified in accordance with Part 491 of this chapter.

(1) Services furnished by a physician within the scope of practice of his profession under State law, if the physician performs the services in the clinic or the services are furnished away from the clinic and the physician has an agreement with the clinic providing that he will be paid by it for such services.

(2) Services furnished by a physician assistant, nurse practitioner, nurse midwife or other specialized nurse practitioner (as defined in §§ 405.2401

and 491.2 of this chapter) if the services are furnished in accordance with the requirements specified in § 405.2414(a) of this chapter.

(3) Services and supplies that are furnished as an incident to professional services furnished by a physician, physician assistant, nurse practitioner, nurse midwife, or specialized nurse practitioner. (See §§ 405.2413 and 405.2415 of this chapter for the criteria for determining whether services and supplies are included under this paragraph.)

(4) Part-time or intermittent visiting nurse care and related medical supplies (other than drugs and biologicals) if:

(i) The clinic is located in an area in which the Secretary has determined that there is a shortage of home health agencies (see § 405.2417 of this chapter);

(ii) The services are furnished by a registered nurse or licensed practical nurse or a licensed vocational nurse employed by, or otherwise compensated for the services by, the clinic;

(iii) The services are furnished under a written plan of treatment that is established and reviewed at least every 60 days by a supervising physician of the clinic or that is established by a physician, physician assistant, nurse practitioner, nurse midwife, or specialized nurse practitioner and reviewed and approved at least every 60 days by a supervising physician of the clinic; and

(iv) The services are furnished to a homebound recipient. For purposes of visiting nurse care, a "homebound" recipient means one who is permanently or temporarily confined to his place of residence because of a medical or health condition. He may be considered homebound if he leaves the place of residence infrequently. For this purpose, "place of residence" does not include a hospital or a skilled nursing facility.

(c) *Other ambulatory services furnished by a rural health clinic.* If the State plan covers rural health clinic services, other ambulatory services means ambulatory services other than rural health clinic services, as defined in paragraph (b) of this section, that are otherwise included in the plan and meet specific State plan requirements for furnishing those services. Other ambulatory services furnishd by a rural health clinic are not subject to the physician supervision requirements specified in § 491.8(b) of this chapter, unless required by State law or the State plan.

[43 FR 45224, Sept. 29, 1978, as amended at 47 FR 21050, May 17, 1982; 52 FR 47934, Dec. 17, 1987]

§ 440.30 Other laboratory and X-ray services.

Other laboratory and X-ray services means professional and technical laboratory and radiological services—

(a) Ordered and provided by or under the direction of a physician or other licensed practitioner of the healing arts within the scope of his practice as defined by State law or ordered and billed by a physician but provided by an independent laboratory;

(b) Provided in an office or similar facility other than a hospital outpatient department or clinic; and

(c) Furnished by a laboratory that meets the Medicare conditions for coverage of services for independent laboratories.

[46 FR 42672, Aug. 24, 1981, as amended at 52 FR 47934, Dec. 17, 1987]

§ 440.40 Skilled nursing facility services for individuals age 21 or older (other than services in an institution for mental diseases), EPSDT, and family planning services and supplies.

(a) *Skilled nursing facility services.* (1) "Skilled nursing facility services for individuals age 21 or older, other than services in an institution for mental diseases", means services that are—

(i) Needed on a daily basis and required to be provided on an inpatient basis under §§ 409.31 through 409.35 of this chapter.

(ii) Provided by (A) a facility or distinct part of a facility that is certified to meet the requirements for participation under Subpart C of Part 442 of this subchapter, as evidenced by a valid agreement between the Medicaid agency and the facility for providing skilled nursing facility services and making payments for services under the plan; or (B) if specified in the State plan, a swing-bed hospital that has an approval from HCFA to furnish skilled nursing facility services in the Medicare program; and

(iii) Ordered by and provided under the direction of a physician.

(2) Skilled nursing facility services includes services provided by any facility located on an Indian reservation and certified by the Secretary as meeting the requirements of Subpart K of Part 405 of this chapter.

(b) *EPSDT.* "Early and periodic screening and diagnosis and treatment" means—

(1) Screening and diagnostic services to determine physical or mental defects in recipients under age 21; and

(2) Health care, treatment, and other measures to correct or ameliorate any defects and chronic conditions discovered. (See Subpart B of Part 441 of this subchapter.)

(c) *Family planning services and supplies for individuals of child-bearing age.* [Reserved]

[43 FR 45224, Sept. 29, 1978, as amended at 47 FR 31532, July 20, 1982; 48 FR 12551, Mar. 25, 1983; 51 FR 22041, June 17, 1986]

§ 440.50 Physicians' services.

"Physicians' services," whether furnished in the office, the recipient's home, a hospital, a skilled nursing facility, or elsewhere, means services provided—

(a) Within the scope of practice of medicine or osteopathy as defined by State law; and

(b) By or under the personal supervision of an individual licensed under State law to practice medicine or osteopathy.

[43 FR 45224, Sept. 29, 1978, as amended at 47 FR 31532, July 20, 1982]

§ 440.60 Medical or other remedial care provided by licensed practitioners.

(a) "Medical care or any other type remedial care provided by licensed practitioners" means any medical or remedial care or services, other than physicians' services, provided by licensed practitioners within the scope of practice as defined under State law.

(b) Chiropractors' services include only services that—

(1) Are provided by a chiropractor who is licensed by the State and meets standards issued by the Secretary under § 405.232(b) of this chapter; and

(2) Consists of treatment by means of manual manipulation of the spine that the chiropractor is legally authorized by the State to perform.

§ 440.70 Home health services.

(a) "Home health services" means the services in paragraph (b) of this section that are provided to a recipient—

(1) At his place of residence, as specified in paragraph (c) of this section; and

(2) On his physician's orders as part of a written plan of care that the physician reviews every 60 days.

(b) Home health services include the following services and items. Those listed in paragraphs (b) (1), (2) and (3) of this section are required services; those in paragraph (b)(4) of this section are optional.

(1) Nursing service, as defined in the State Nurse Practice Act, that is provided on a part-time or intermittent basis by a home health agency as defined in paragraph (d) of this section, or if there is no agency in the area, a registered nurse who—

(i) Is currently licensed to practice in the State;

(ii) Receives written orders from the patient's physician;

(iii) Documents the care and services provided; and

(iv) Has had orientation to acceptable clinical and administrative recordkeeping from a health department nurse.

(2) Home health aide service provided by a home health agency,

(3) Medical supplies, equipment, and appliances suitable for use in the home, and

(4) Physical therapy, occupational therapy, or speech pathology and audiology services, provided by a home health agency or by a facility licensed by the State to provide medical rehabilitation services. (See § 441.15 of this subchapter.)

(c) A recipient's place of residence, for home health services, does not include a hospital, skilled nursing facility, or intermediate care facility except for home health services in an intermediate care facility that are not required to be provided by the facility under Subparts F and G of Part 442 of this subchapter. For example, a registered nurse may provide short-term care for a recipient in an intermediate care facility during an acute illness to avoid the recipient's transfer to a skilled nursing facility.

(d) "Home health agency" means a public or private agency or organization, or part of an agency or organization, that meets requirements for participation in Medicare.

(e) A "facility licensed by the State to provide medical rehabilitation services" means a facility that—

(1) Provides therapy services for the primary purpose of assisting in the rehabilitation of disabled individuals through an integrated program of—

(i) Medical evaluation and services; and

(ii) Psychological, social, or vocational evaluation and services; and

(2) Is operated under competent medical supervision either—

(i) In connection with a hospital; or

(ii) As a facility in which all medical and related health services are prescribed by or under the direction of individuals licensed to practice medicine or surgery in the State.

[43 FR 45224, Sept. 29, 1978, as amended at 45 FR 24888, Apr. 11, 1980]

§ 440.80 Private duty nursing services.

Private duty nursing services means nursing services for recipients who require more individual and continuous care than is available from a visiting nurse or routinely provided by the nursing staff of the hospital or skilled nursing facility. These services are provided—

(a) By a registered nurse or a licensed practical nurse;

(b) Under the direction of the recipient's physician; and

(c) To a recipient in one or more of the following locations at the option of the State—

(1) His or her own home;

(2) A hospital; or

(3) A skilled nursing facility.

[52 FR 47934, Dec. 17, 1987]

§ 440.90 Clinic services.

"Clinic services" means preventive, diagnostic, therapeutic, rehabilitative, or palliative items or services that—

(a) Are provided to outpatients;

(b) Are provided by a facility that is not part of a hospital but is organized and operated to provide medical care to outpatients; and

(c) Except in the case of nurse-midwife services, as specified in § 440.165, are furnished by or under the direction of a physician or dentist.

[47 FR 21050, May 17, 1982]

§ 440.100 Dental services.

(a) "Dental services" means diagnostic, preventive, or corrective procedures provided by or under the supervision of a dentist in the practice of his profession, including treatment of—

(1) The teeth and associated structures of the oral cavity; and

(2) Disease, injury, or impairment that may affect the oral or general health of the recipient.

(b) "Dentist" means an individual licensed to practice dentistry or dental surgery.

[43 FR 45224, Sept. 29, 1978, as amended at 45 FR 24888, Apr. 11, 1980]

§ 440.110 Physical therapy, occupational therapy, and services for individuals with speech, hearing, and language disorders.

(a) *Physical therapy.* (1) "Physical therapy" means services prescribed by a physician and provided to a recipient by or under the direction of a qualified physical therapist. It includes any necessary supplies and equipment.

(2) A "qualified physical therapist" is an individual who is—

(i) A graduate of a program of physical therapy approved by both the Council on Medical Education of the American Medical Association and the American Physical Therapy Association or its equivalent; and

(ii) Where applicable, licensed by the State.

(b) *Occupational therapy.* (1) "Occupational therapy" means services prescribed by a physician and provided to a recipient by or under the direction of a qualified occupational therapist. It includes any necessary supplies and equipment.

(2) A "qualified occupation therapist" is an individual who is—

(i) Registered by the American Occupational Therapy Association; or

(ii) A graduate of a program in occupational therapy approved by the Council on Medical Education of the American Medical Association and engaged in the supplemental clinical experience required before registration by the American Occupational Therapy Association.

(c) *Services for individuals with speech, hearing, and language disorders.* (1) "Services for individuals with speech, hearing, and language disorders" means diagnostic, screening, preventive, or corrective services provided by or under the direction of a speech pathologist or audiologist, for which a patient is referred by a physician. It includes any necessary supplies and equipment.

(2) A "speech pathologist or audiologist" is an individual who—

(i) Has a certificate of clinical competence from the American Speech and Hearing Association;

(ii) Has completed the equivalent educational requirements and work experience necessary for the certificate; or

(iii) Has completed the academic program and is acquiring supervised work experience to qualify for the certificate.

[43 FR 45224, Sept. 29, 1978, as amended at 45 FR 24888, Apr. 11, 1980]

§ 440.120 Prescribed drugs, dentures, prosthetic devices, and eyeglasses.

(a) "Prescribed drugs" means simple or compound substances or mixtures of substances prescribed for the cure, mitigation, or prevention of disease, or for health maintenance that are—

(1) Prescribed by a physician or other licensed practitioner of the healing arts within the scope of this professional practice as defined and limited by Federal and State law;

(2) Dispensed by licensed pharmacists and licensed authorized practitioners in accordance with the State Medical Practice Act; and

(3) Dispensed by the licensed pharmacist or practitioner on a written prescription that is recorded and maintained in the pharmacist's or practitioner's records.

(b) "Dentures" are artificial structures made by or under the direction of a dentist to replace a full or partial set of teeth.

(c) "Prosthetic devices" means replacement, corrective, or supportive devices prescribed by a physician or other licensed practitioner of the healing arts within the scope of his practice as defined by State law to—

(1) Artificially replace a missing portion of the body;

(2) Prevent or correct physical deformity or malfunction; or

(3) Support a weak or deformed portion of the body.

(d) "Eyeglasses" means lenses, including frames, and other aids to vision prescribed by a physician skilled in diseases of the eye or an optometrist.

§ 440.130 Diagnostic, screening, preventive, and rehabilitative services.

(a) "Diagnostic services," except as otherwise provided under this subpart, includes any medical procedures or supplies recommended by a physician or other licensed practitioner of the healing arts, within the scope of his practice under State law, to enable him to identify the existence, nature, or extent of illness, injury, or other health deviation in a recipient.

(b) "Screening services" means the use of standardized tests given under medical direction in the mass examination of a designated population to detect the existence of one or more particular diseases or health deviations or to identify for more definitive studies individuals suspected of having certain diseases.

(c) "Preventive services" means services provided by a physician or other licensed practitioner of the healing arts within the scope of his practice under State law to—

(1) Prevent disease, disability, and other health conditions or their progression;

(2) Prolong life; and

(3) Promote physical and mental health and efficiency.

(d) "Rehabilitative services," except as otherwise provided under this subpart, includes any medical or remedial services recommended by a physician or other licensed practitioner of the healing arts, within the scope of his practice under State law, for maximum reduction of physical or mental disability and restoration of a recipient to his best possible functional level.

§ 440.140 Inpatient hospital services, skilled nursing facility services, and intermediate care facility services for individuals age 65 or older in institutions for mental diseases.

(a) *Inpatient hospital services.* (1) "Inpatient hospital services for individuals age 65 or older in institutions for mental diseases" means services provided under the direction of a physician for the care and treatment of recipients in an institution for mental diseases that meets the requirements specified in § 482.60(b), (c), and (e) of this chapter and—

(i) Meets the requirements for utilization review in § 482.30(a), (b), (d), and (e) of this chapter; or

(ii) Has been granted a waiver of those utilization review requirements under section 1903(i)(4) and Subpart H of Part 456 of this subchapter.

(2) "Institution for mental diseases" means an institution that is primarily engaged in providing diagnosis, treatment, or care of individuals with mental diseases, including medical care, nursing care, and related services.

(b) *Skilled nursing facility services.* "Skilled nursing facility services for individuals age 65 or older in institutions for mental diseases" means skilled nursing facility services as defined in § 440.40 that are provided in institutions for mental diseases, as defined in paragraph (a) of this section.

(c) *Intermediate care facility services.* "Intermediate care facility services for individuals age 65 or older in institutions for mental diseases" means intermediate care facility services as defined in § 440.150 of this subpart, that are provided to recipients who are—

(1) Determined under §§ 456.360 through 456.372 of this subchapter to be in need of services; and

(2) In institutions for mental diseases, as defined in paragraph (a) of this section.

[51 FR 22041, June 17, 1986]

§ 440.150 Intermediate care facility services, other than in institutions for mental diseases.

(a) "Intermediate care facility services, other than in an institution for mental diseases" means services provided in a facility that—

(1) Fully meets the requirements for a State license to provide, on a regular basis, health-related services to individuals who do not require hospital or skilled nursing facility care, but whose mental or physical condition requires services that—

(i) Are above the level of room and board; and

(ii) Can be made available only through institutional facilities,

(2) Has been certified to meet the requirements of Subpart C of Part 442 of this subchapter as evidenced by a valid agreement between the Medicaid agency and the facility for providing intermediate care facility services and making payments for services under the plan; and

(3) Meets the conditions of Subpart E of Part 442 of this subchapter.

(b) "Intermediate care facility services" include services—

(1) Considered appropriate by the State and provided by a Christian Science sanatorium operated, or listed and certified, by the First Church of Christ, Scientist, Boston, Mass.; or

(2) Provided by a facility located on an Indian reservation that—

(i) Furnishes, on a regular basis, health-related services; and

(ii) Is certified by the Secretary to meet the standards in Subpart E of Part 442 of this subchapter.

(c) "Intermediate care facility services" may include services in an institution for the mentally retarded or persons with related conditions if—

(1) The primary purpose of the institution is to provide health or rehabilitative services for mentally retarded

individuals or persons with related conditions;

(2) The institution meets the standards in Subpart E of Part 442 of this subchapter; and

(3) The mentally retarded recipient for whom payment is requested is receiving active treatment as specified in §483.440.

(d) "Intermediate care facility services" mav include services provided in a distinct part of a facility other than an intermediate care facility if the distinct part—

(1) Meets all requirements for an intermediate care facility;

(2) Is an identifiable unit, such as an entire ward or contiguous ward, a wing, floor, or building;

(3) Consists of all beds and related facilities in the unit;

(4) Houses all recipients for whom payment is being made for intermediate care facility services, except as provided in paragraph (e) of this section;

(5) Is clearly identified; and

(6) Is approved in writing by the survey agency.

(e) If a State includes as intermediate care facility services those services provided by a distinct part of a facility other than an intermediate care facility, it may not require transfer of a recipient within or between facilities if, in the opinion of the attending physician, it might be harmful to the physical or mental health of the recipient.

(f) Intermediate care facility services may include services provided in a swing-bed hospital that has an approval to furnish intermediate care services.

[43 FR 45224, Sept. 29, 1978, as amended at 47 FR 31532, July 20, 1982; 51 FR 22041, June 17, 1986; 53 FR 20495, June 3, 1988]

EFFECTIVE DATE NOTE: At 53 FR 20495, June 3, 1988, §440.150(c)(3) was amended by removing the phrase "defined in §435.1009" and adding in its place the phrase "specified in §483.440", effective October 3, 1988.

§ 440.160 Inpatient psychiatric services for individuals under age 21.

"Inpatient psychiatric services for individuals under age 21" means services that—

(a) Are provided under the direction of a physician;

(b) Are provided in a facility or program accredited by the Joint Commission on Accreditation of Hospitals; and

(c) Meet the requirements in Subpart D of Part 441.

§ 440.165 Nurse-midwife service.

(a) "Nurse-midwife services" means services that—

(1) Are concerned with management of the care of mothers and newborns throughout the maternity cycle;

(2) Are furnished by a nurse-midwife within the scope of practice authorized by State law or regulation and, in the case of inpatient or outpatient hospital services or clinic services, are furnished by or under the direction of a nurse-midwife to the extent permitted by the facility; and

(3) Unless required by State law or regulations or a facility, are reimbursed without regard to whether the nurse-midwife is under the supervision of, or associated with, a physician or other health care provider. (See § 441.21 of this chapter for provisions on independent provider agreements for nurse-midwives.)

(b) "Nurse-midwife" means a registered professional nurse who meets the following requirements:

(1) Is currently licensed to practice in the State as a registered professional nurse.

(2) Is legally authorized under State law or regulations to practice as a nurse-midwife.

(3) Except as provided in paragraph (b)(4) of this section, has completed a program of study and clinical experience for nurse-midwives, as specified by the State.

(4) If the State does not specify a program of study and clinical experience that nurse-midwives must complete to practice in that State, meets one of the following conditions:

(i) Is currently certified as a nurse-midwife by the American College of Nurse-Midwives.

(ii) Has satisfactorily completed a formal educational program (of at least one academic year) that, upon completion, qualifies the nurse to take the certification examination offered by the American College of Nurse-Midwives.

(iii) Has successfully completed a formal educational program for preparing registered nurses to furnish gynecological and obstetrical care to women during pregnancy, delivery, and the postpartum period, and care to normal newborns, and was practicing as a nurse-midwife for a total of 12 months during any 18-month period from August 8, 1976 to July 16, 1982.

(c) "Maternity cycle" means a period limited to—

(1) Pregnancy;

(2) Labor;

(3) Birth; and

(4) The immediate postpartum period, not to exceed six weeks.

[47 FR 21050, May 17, 1982; 47 FR 23448, May 28, 1982]

§ 440.170 Any other medical care or remedial care recognized under State law and specified by the Secretary.

(a) *Transportation.* (1) "Transportation" includes expenses for transportation and other related travel expenses determined to be necessary by the agency to secure medical examinations and treatment for a recipient.

(2) Transportation, as defined in this section, is furnished only by a provider to whom a direct vendor payment can appropriately be made by the agency. If other arrangements are made to assure transportation under § 431.53 of this subchapter, FFP is available as an administrative cost.

(3) "Travel expenses" include—

(i) The cost of transportation for the recipient by ambulance, taxicab, common carrier, or other appropriate means;

(ii) The cost of meals and lodging en route to and from medical care, and while receiving medical care; and

(iii) The cost of an attendant to accompany the recipient, if necessary, and the cost of the attendant's transportation, meals, lodging, and, if the attendant is not a member of the recipient's family, salary.

(b) *Services of Christian Science nurses.* "Services of Christian Science nurses" mean services provided by nurses who are listed and certified by the First Church of Christ, Scientist, Boston, Mass., if—

(1) The services have been requested by the recipient; and

(2) The services are provided—

(i) By or under the supervision of a Christian Science visiting nurse organization listed and certified by the First Church of Christ, Scientist, Boston, Mass.; or

(ii) As private duty services to a recipient in his own home or in a Christian Science sanatorium operated, or listed and certified, by the First Church of Christ, Scientist, Boston, Mass., if the recipient requires individual and continuous care beyond that available from a visiting nurse or that routinely provided by the nursing staff of the sanatorium.

(c) *Services in Christian Science sanatoriums.* "Services in Christian Science sanatoriums" means services provided in Christian Science sanatoriums that are operated by, or listed and certified by, the First Church of Christ, Scientist, Boston, Mass.

(d) *Skilled nursing facility services for individuals under age 21.* "Skilled nursing facility services for individuals under 21" means those services specified in § 440.40 that are provided to recipients under 21 years of age.

(e) *Emergency hospital services.* "Emergency hospital services" means services that—

(1) Are necessary to prevent the death or serious impairment of the health of a recipient; and

(2) Because of the threat to the life or health of the recipient necessitate the use of the most accessible hospital available that is equipped to furnish the services, even if the hospital does not currently meet—

(i) The conditions for participation under Medicare; or

(ii) The definitions of inpatient or outpatient hospital services under §§ 440.10 and 440.20.

(f) *Personal care services in a recipient's home.* Unless defined differently by a State agency for purposes of a waiver granted under Part 441, Subpart G of this chapter, "personal care services in a recipient's home" means services prescribed by a physician in accordance with the recipient's plan of treatment and provided by an individual who is—

(1) Qualified to provide the services;

(2) Supervised by a registered nurse; and

(3) Not a member of the recipient's family.

[43 FR 45224, Sept. 29, 1978, as amended at 45 FR 24889, Apr. 11, 1980; 46 FR 48540, Oct. 1, 1981]

§ 440.180 Home or community-based services.

"Home or community-based services" means services, not otherwise furnished under the State's Medicaid plan, that are furnished under a waiver granted under the provisions of Part 441, Subpart G of this subchapter. Except as provided in § 441.310 the services may consist of any of the following services as defined by the agency that meet the standards specified in § 441.302(a):

(a) Case management services;

(b) Homemaker services;

(c) Home health aide services;

(d) Personal care services;

(e) Adult day health services;

(f) Habilitation services;

(g) Respite care services;

(h) Other services requested by the Medicaid agency and approved by HCFA as cost-effective.

[50 FR 10026, Mar. 13, 1985]

Subpart B—Requirements and Limits Applicable to All Services

§ 440.200 Basis, purpose, and scope.

(a) This subpart implements—

(1) Section 1902(a)(10), regarding comparability of services for groups of recipients, and the amount, duration, and scope of services described in section 1905(a) of the Act that the State plan must provide for recipients;

(2) Section 1902(a)(22)(D), which provides for standards and methods to assure quality of services;

(3) Section 1907 on observance of religious beliefs; and

(4) Section 1915 on exceptions to section 1902(a)(10) and waivers of other requirements of section 1902 of the Act.

(b) The requirements and limits of this subpart apply for all services defined in Subpart A of this part.

[46 FR 48528, Oct. 1, 1981]

§ 440.210 Required services for the categorically needy.

A State plan must specify that, as a minimum, categorically needy recipients are provided the services as specified in §§ 440.10 through 440.50, 440.70, and (to the extent nurse-midwives are authorized to practice under State law or regulation) 440.165.

[47 FR 21050, May 17, 1982]

§ 440.220 Required services for the medically needy.

A State plan that includes the medically needy must specify that the medically needy are provided, as a minimum, the following services:

(a) Prenatal care and delivery services for pregnant women.

(b) Ambulatory services, as defined in the State plan, for—

(1) Individuals under age 18; and

(2) Individuals entitled to institutional services.

(c) Home health services (§ 440.70) to any individual entitled to skilled nursing facility services.

(d) If the State plan includes services in an institution for mental diseases (§ 440.140 or § 440.160) or in an intermediate care facility for the mentally retarded (§ 440.150(c)) for any group of medically needy, either of the following sets of services to each of the medically needy groups:

(1) The services contained in §§ 440.10 through 440.50 and (to the extent nurse-midwives are authorized to practice under State law or regulation) 440.165; or

(2) The services contained in any seven of the sections in §§ 440.10 through 440.165.

[46 FR 47992, Sept. 30, 1981; 46 FR 54744, Nov. 4, 1981, as amended at 47 FR 21050, May 17, 1982]

§ 440.230 Sufficiency of amount, duration, and scope.

(a) The plan must specify the amount, duration, and scope of each service that it provides for—

(1) The categorically needy; and

(2) Each covered group of medically needy.

(b) Each service must be sufficient in amount, duration, and scope to reasonably achieve its purpose.

(c) The Medicaid agency may not arbitrarily deny or reduce the amount, duration, or scope of a required service under §§ 440.210 and 440.220 to an otherwise eligible recipient solely because of the diagnosis, type of illness, or condition.

(d) The agency may place appropriate limits on a service based on such criteria as medical necessity or on utilization control procedures.

[46 FR 47993, Sept. 30, 1981]

§ 440.240 Comparability of services for groups.

Except as limited in § 440.250—

(a) The plan must provide that the services available to any categorically needy recipient under the plan are not less in amount, duration, and scope than those services available to a medically needy recipient; and

(b) The plan must provide that the services available to any individual in the following groups are equal in amount, duration, and scope for all recipients within the group:

(1) The categorically needy.

(2) A covered medically needy group.

[46 FR 47993, Sept. 30, 1981]

§ 440.250 Limits on comparability of services.

(a) Skilled nursing facility services (§ 440.40(a)) may be limited to recipients age 21 or older.

(b) Early and periodic screening, diagnosis, and treatment (§ 440.40(b)) must be limited to recipients under age 21.

(c) Family planning services and supplies must be limited to recipients of childbearing age, including minors who can be considered sexually active and who desire the services and supplies.

(d) If covered under the plan, services to recipients in institutions for mental diseases (§ 440.140) must be limited to those age 65 or older.

(e) If covered under the plan, inpatient psychiatric services (§ 440.160) must be limited to recipients under age 22 as specified in § 441.151(c) of this subchapter.

(f) If Medicare benefits under Part B of title XVIII are made available to recipients through a buy-in agreement or payment of premiums, or part or all of the deductibles, cost sharing or similar charges, they may be limited to recipients who are covered by the agreement or payment.

(g) If services in addition to those offered under the plan are made available under a contract between the agency or political subdivision and an organization providing comprehensive health services, those additional services may be limited to recipients who reside in the geographic area served by the contracting organization and who elect to receive services from it.

(h) Ambulatory services for the medically needy (§ 440.220(b)) may be limited to—

(1) Individuals under age 18; and

(2) Individuals entitled to institutional services.

(i) Services provided under an exception to requirements allowed under § 431.54 may be limited as provided under that exception.

(j) If HCFA has approved a waiver of Medicaid requirements under § 431.55, services may be limited as provided by the waiver.

(k) If the agency has been granted a waiver of the requirements of § 440.240 (Comparability of services) in order to provide home or community-based services under § 440.180, the services provided under the waiver need not be comparable for all individuals within a group.

(l) If the agency imposes cost sharing on recipients in accordance with 447.53, the imposition of cost sharing on an individual who is not exempted by one of the conditions in section 447.53(b) shall not require the State to impose copayments on an individual who is eligible for such exemption.

[43 FR 45224, Sept. 29, 1978, as amended at 45 FR 24889, Apr. 11, 1980; 46 FR 48541, Oct. 1, 1981; 48 FR 5735, Jan. 8, 1983; 51 FR 22041, June 17, 1986]

§ 440.260 Methods and standards to assure quality of services.

The plan must include a description of methods and standards used to assure that services are of high quality.

§ 440.270 Religious objections.

(a) Except as specified in paragraph (b) of this section, the agency may not require any individual to undergo any medical service, diagnosis, or treatment or to accept any other health service provided under the plan if the individual objects, or in the case of a child, a parent or guardian objects, on religious grounds.

(b) If a physical examination is necessary to establish eligibility based on disability or blindness, the agency may not find an individual eligible for Medicaid unless he undergoes the examination.

PART 441—SERVICES: REQUIREMENTS AND LIMITS APPLICABLE TO SPECIFIC SERVICES

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AUTHORITY: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

SOURCE: 43 FR 45229, Sept. 29, 1978, unless otherwise noted.

§ 441.1 Purpose.

This part sets forth State plan requirements and limits on FFP for specific services defined in Part 440 of this subchapter. Standards for payments for services provided in intermediate care facilities and skilled nursing facilities are set forth in Part 442 of this subchapter.

Subpart A—General Provisions

§ 441.10 Basis.

This subpart is based on the following sections of the Act which state requirements and limits on the services specified or provide Secretarial authority to prescribe regulations relating to services:

(a) Sections 1902(a)(10)(D) and 1905(a)(7) for home health services (§ 441.15).

(b) Section 1905(a)(4)(C) for family planning (§ 441.20).

(c) Section 1905(a)(12) and (e) for optometric services (§ 441.30).

(d) Section 1102 for end-stage renal disease (§ 441.40).

(e) Section 1905(a) (following (a)(18)), which prohibits FFP in expenditures for certain services (§ 441.13).

(f) Section 1903(i)(5) for certain prescribed drugs (§ 441.25).

(g) Section 1903(i)(6) which prohibits (except in emergency situations) FFP in expenditures for inpatient hospital tests that are not ordered by the attending physician or other licensed practitioner (§ 441.12).

(h) Section 1905 (a)(17) and (m) for nurse-midwife services (§ 441.21).

(i) Section 1138(b) for organ procurement organization services (§ 441.13(c)).

[43 FR 45229, Sept. 29, 1978, as amended at 45 FR 24889, Apr. 11, 1980; 46 FR 47993, Sept. 30, 1981; 46 FR 48554, Oct. 1, 1981; 47 FR 21051, May 17, 1982; 47 FR 31878, July 23, 1982; 53 FR 6549, March 1, 1988]

§ 441.11 Continuation of FFP for institutional services.

(a) *Basic conditions for continuation of FFP.* FFP may be continued for up to 30 days after the effective date of termination or expiration of a provider agreement, or after an administrative hearing decision that upholds the agency's termination or nonrenewal action, if the following conditions are met:

(1) The Medicaid payments are for recipients admitted to the facility before the effective date of termination or expiration.

(2) The Medicaid agency is making reasonable efforts to transfer those recipients to other facilities or to alternate care.

(b) *When the 30-day period begins.* The 30-day period begins on either of the following:

(1) The effective date of termination or nonrenewal of the facility's Medicare provider agreement by HCFA, or of its Medicaid provider agreement as instructed by HCFA.

(2) The later of—

(i) The effective date of termination or nonrenewal of the facility's Medicaid provider agreement by the Medicaid agency on is own volition; or

(ii) The date of issuance of an administrative hearing decision that upholds the agency's termination or nonrenewal action.

(c) *Services for which FFP may be continued.* FFP may be continued for any of the following services, as defined in Subpart A of Part 440 of this chapter:

(1) Inpatient hospital services.

(2) Inpatient hospital services for individuals age 65 or older in an institution for mental diseases.

(3) Skilled nursing facility services for individuals age 21 or older.

(4) Skilled nursing facility services for individuals age 65 or older in an institution for mental diseases.

(5) Intermediate care facility services.

(6) Intermediate care facility services for individuals age 65 or over in an institution for mental diseases.

(7) Inpatient psychiatric services for individuals under age 21.

[52 FR 32550, Aug. 28, 1987]

§ 441.12 Inpatient hospital tests.

Except in an emergency situation (see § 440.170(e)(1) of this chapter for definition), FFP is not available in expenditures for inpatient hospital tests unless the tests are specifically ordered by the attending physician or other licensed practitioner, acting within the scope of practice as defined under State law, who is responsible for the diagnosis or treatment of a particular patient's condition.

[46 FR 48554, Oct. 1, 1981]

§ 441.13 Prohibitions on FFP.

(a) FFP is not available in expenditures for services for—

(1) Any individual who is in a public institution, as defined in § 435.1009 of this subchapter; or

(2) Any individual who is under age 65 and is in an institution for mental diseases, except an individual who is under age 22 and receiving inpatient psychiatric services under Subpart D of this part.

(b) Payments to institutions for the mentally retarded or persons with related conditions and to psychiatric facilities or programs providing inpatient psychiatric services to individuals under age 21 may not include reimbursement for vocational training and educational activities.

(c) FFP is not available in expenditures for services furnished by an organ procurement organization on or after April 1, 1988, that does not meet the requirements of Part 485, Subpart D of this chapter.

[43 FR 45229, Sept. 29, 1978, as amended at 51 FR 22041, June 17, 1986; 53 FR 6549, March 1, 1988]

§ 441.15 Home health services.

With respect to the services defined in § 440.70 of this subchapter, a State plan must provide that—

(a) Home health services include, as a minimum—

(1) Nursing services;

(2) Home health aide services; and

(3) Medical supplies, equipment, and appliances.

(b) The agency provides home health services to—

(1) Categorically needy recipients age 21 or over;

(2) Categorically needy recipients under age 21, if the plan provides skilled nursing facility services for them; individuals; and

(3) Medically needy recipients to whom skilled nursing facility services are provided under the plan.

(c) The eligibility of a recipient to receive home health services does not depend on his need for or discharge from institutional care.

[43 FR 45229, Sept. 29, 1978, as amended at 45 FR 24889, Apr. 11, 1980]

§ 441.20 Family planning services.

For recipients eligible under the plan for family planning services, the plan must provide that each recipient is free from coercion or mental pressure and free to choose the method of family planning to be used.

§ 441.21 Nurse-midwife services.

If a State plan, under § 440.210 or 440.220 of this subchapter, provides for nurse-midwife services, as defined in § 440.165, the plan must provide that the nurse-midwife may enter into an independent provider agreement, without regard to whether the nurse-midwife is under the supervision of, or associated with, a physician or other health care provider.

[47 FR 21051, May 17, 1982]

§ 441.25 Prohibition on FFP for certain prescribed drugs.

(a) FFP is not available in expenditures for the purchase or administration of any drug product that meets all of the following conditions:

(1) The drug product was approved by the Food and Drug Administration (FDA) before October 10, 1962.

(2) The drug product is available only through prescription.

(3) The drug product is the subject of a notice of opportunity for hearing issued under section 505(e) of the Federal Food, Drug, and Cosmetic Act and published in the FEDERAL REGISTER on a proposed order of FDA to withdraw its approval for the drug product because it has determined that the product is less than effective for all its labeled indications.

(4) The drug product is presently not subject to a determination by FDA, made under its efficacy review program (see 21 CFR 310.6 for an explanation of this program), that there is a compelling justification of the drug product's medical need.

(b) FFP is not available in expenditures for the purchase or administration of any drug product that is identical, related, or similar, as defined in 21 CFR 310.6, to a drug product that meets the conditions of paragraph (a) of this section.

[46 FR 48554, Oct. 1, 1981]

§ 441.30 Optometric services.

The plan must provide for payment of optometric services as physician services, whether furnished by an optometrist or a physician, if—

(a) The plan does not provide for payment for services provided by an optometrist, except for eligibility determinations under §§ 435.531 and 436.531 of this subchapter, but did provide for those services at an earlier period; and

(b) The plan specifically provides that physicians' services include services an optometrist is legally authorized to perform.

§ 441.40 End-stage renal disease.

FFP in expenditures for services described in Subpart A of Part 440 is available for facility treatment of end-stage renal disease only if the facility has been approved by the Secretary to furnish those services under Medicare. This requirement for approval of the facility does not apply under emergency conditions permitted under Medicare (see § 482.2 of this chapter).

[43 FR 45229, Sept. 29, 1978, as amended at 51 FR 22041, June 17, 1986]

Subpart B—Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) of Individuals Under Age 21

SOURCE: 49 FR 43666, Oct. 31, 1984, unless otherwise noted.

§ 441.50 Basis and purpose.

This subpart implements sections 1902(a)(43) and 1905(a)(4)(B) of the Social Security Act, by prescribing State plan requirements for providing early and periodic screening and diagnosis of eligible Medicaid recipients under age 21 to ascertain physical and mental defects, and providing treatment to correct or ameliorate defects and chronic conditions found.

§ 441.55 State plan requirements.

A State plan must provide that the Medicaid agency meets the requirements of §§ 441.56–441.62, with respect to EPSDT services, as defined in § 440.40(b) of this subchapter.

§ 441.56 Required activities.

(a) *Informing.* The agency must—

(1) Provide for a combination of written and oral methods designed to inform effectively all EPSDT eligible individuals (or their families) about the EPSDT program.

(2) Using clear and nontechnical language, provide information about the following—

(i) The benefits of preventive health care;

(ii) The services available under the EPSDT program and where and how to obtain those services;

(iii) That the services provided under the EPSDT program are without cost to eligible individuals under 18 years of age, and if the agency chooses, to those 18 or older, up to age 21, except for any enrollment fee, premium, or similar charge that may be imposed on medically needy recipients; and

(iv) That necessary transportation and scheduling assistance described in § 441.62 of this subpart is available to the EPSDT eligible individual upon request.

(3) Effectively inform those individuals who are blind or deaf, or who cannot read or understand the English language.

(4) Provide assurance to HCFA that processes are in place to effectively inform individuals as required under this paragraph, generally, within 60 days of the individual's initial Medicaid eligibility determination and in the case of families which have not utilized EPSDT services, annually thereafter.

(b) *Screening.* (1) The agency must provide to eligible EPSDT recipients who request it, screening (periodic comprehensive child health assessments); that is, regularly scheduled examinations and evaluations of the general physical and mental health, growth, development, and nutritional status of infants, children, and youth. (See paragraph (c)(3) of this section for requirements relating to provision of immunization at the time of screening.) As a minimum, these screenings must include, but are not limited to:

(i) Comprehensive health and developmental history.

(ii) Comprehensive unclothed physical examination.

(iii) Appropriate vision testing.

(iv) Appropriate hearing testing.

(v) Appropriate laboratory tests.

(vi) Dental screening services furnished by direct referral to a dentist for children beginning at 3 years of age. An agency may request from HCFA an exception from this age requirement (within an outer limit of age 5) for a two year period and may request additional two year exceptions. If an agency requests an exception, it must demonstrate to HCFA's satisfaction that there is a shortage of dentists that prevents the agency from meeting the age 3 requirement.

(2) Screening services in paragraph (b)(1) of this section must be provided in accordance with reasonable standards of medical and dental practice determined by the agency after consultation with recognized medical and dental organizations involved in child health care.

(c) *Diagnosis and treatment.* In addition to any diagnostic and treatment services included in the plan, the agency must provide to eligible EPSDT recipients, the following services, the need for which is indicated by screening, even if the services are not included in the plan—

(1) Diagnosis of and treatment for defects in vision and hearing, including eyeglasses and hearing aids;

(2) Dental care, at as early an age as necessary, needed for relief of pain and infections, restoration of teeth and maintenance of dental health; and

(3) Appropriate immunizations. (If it is determined at the time of screening that immunization is needed and appropriate to provide at the time of screening, then immunization treatment must be provided at that time.)

(d) *Accountability.* The agency must maintain as required by §§ 431.17 and 431.18—

(1) Records and program manuals;

(2) A description of its screening package under paragraph (b) of this section; and

(3) Copies of rules and policies describing the methods used to assure that the informing requirement of paragraph (a)(1) of this section is met.

(e) *Timeliness.* With the exception of the informing requirements specified in paragraph (a) of this section, the agency must set standards for the timely provision of EPSDT services which meet reasonable standards of medical and dental practice, as determined by the agency after consultation with recognized medical and dental organizations involved in child health care, and must employ processes to ensure timely initiation of treatment, if required, generally within an outer limit of 6 months after the request for screening services.

[49 FR 43666, Oct. 31, 1984; 49 FR 45431, Nov. 16, 1984]

§ 441.57 Discretionary services.

Under the EPSDT program, the agency may provide for any other medical or remedial care specified in Part 440 of this subchapter, even if the agency does not otherwise provide for these services to other recipients or provides for them in a lesser amount, duration, or scope.

§ 441.58 Periodicity schedule.

The agency must implement a periodicity schedule for screening services that—

(a) Meets reasonable standards of medical and dental practice determined by the agency after consultation with recognized medical and dental organizations involved in child health care;

(b) Specifies screening services applicable at each stage of the recipient's life, beginning with a neonatal examination, up to the age at which an individual is no longer eligible for EPSDT services; and

(c) At the agency's option, provides for needed screening services as determined by the agency, in addition to the otherwise applicable screening services specified under paragraph (b) of this section.

§ 441.59 Treatment of requests for EPSDT screening services.

(a) The agency must provide the screening services described in § 441.56(b) upon the request of an eligible recipient.

(b) To avoid duplicate screening services, the agency need not provide requested screening services to an EPSDT eligible if written verification exists that the most recent age-appropriate screening services, due under the agency's periodicity schedule, have already been provided to the eligible.

§ 441.60 Continuing care.

(a) *Continuing care provider.* For purposes of this subpart, a continuing care provider means a provider who has an agreement with the Medicaid agency to provide reports as required under paragraph (b) of this section and to provide at least the following services to eligible EPSDT recipients formally enrolled with the provider:

(1) With the exception of dental services required under § 441.56, screening, diagnosis, treatment, and referral for follow-up services as required under this subpart.

(2) Maintenance of the recipient's consolidated health history, including information received from other providers.

(3) Physicians' services as needed by the recipient for acute, episodic or chronic illnesses or conditions.

(4) At the provider's option, provision of dental services required under § 441.56 or direct referral to a dentist to provide dental services required under § 441.56(b)(1)(vi). The provider must specify in the agreement whether dental services or referral for dental services are provided. If the provider does not choose to provide either service, then the provider must refer recipients to the agency to obtain those dental services required under § 441.56.

(5) At the provider's option, provision of all or part of the transportation and scheduling assistance as required under § 441.62. The provider must specify in the agreement the transportation and scheduling assistance to be furnished. If the provider does not choose to provide some or all of the assistance, then the provider must refer recipients to the agency to obtain the transportation and scheduling assistance required under § 441.62.

(b) *Reports.* A continuing care provider must provide to the agency any reports that the agency may reasonably require.

(c) *State monitoring.* If the State plan provides for agreements with continuing care providers, the agency must employ methods described in the State plan to assure the providers' compliance with their agreements.

(d) *Effect of agreement with continuing care providers.* Subject to the requirements of paragraphs (a), (b), and (c) of this section, HCFA will deem the agency to meet the requirements of this subpart with respect to all EPSDT eligible recipients formally enrolled with the continuing care provider. To be formally enrolled, a recipient or recipient's family agrees to use one continuing care provider to be a regular source of the described set of services for a stated period of time. Both the recipient and the provider must sign statements that reflect their obligations under the continuing care arrangement.

(e) If the agreement in paragraph (a) of this section does not provide for all or part of the transportation and scheduling assistance required under

§ 441.62, or for dental service under § 441.56, the agency must provide for those services to the extent they are not provided for in the agreement.

§ 441.61 Utilization of providers and coordination with related programs.

(a) The agency must provide referral assistance for treatment not covered by the plan, but found to be needed as a result of conditions disclosed during screening and diagnosis. This referral assistance must include giving the family or recipient the names, addresses, and telephone numbers of providers who have expressed a willingness to furnish uncovered services at little or no expense to the family.

(b) The agency must make available a variety of individual and group providers qualified and willing to provide EPSDT services.

(c) The agency must make appropriate use of State health agencies, State vocational rehabilitation agencies, and Title V grantees (Maternal and Child Health/Crippled Children's Services). Further, the agency should make use of other public health, mental health, and education programs and related programs, such as Head Start, Title XX (Social Services) programs, and the Special Supplemental Food Program for Women, Infants and Children (WIC), to ensure an effective child health program.

§ 441.62 Transportation and scheduling assistance.

The agency must offer to the family or recipient, and provide if the recipient requests—

(a) Necessary assistance with transportation as required under § 431.53 of this chapter; and

(b) Necessary assistance with scheduling appointments for services.

Subpart C—Medicaid for Individuals Age 65 or Over in Institutions for Mental Diseases

Source: 44 FR 17940, Mar. 23, 1979, unless otherwise noted.

§ 441.100 Basis and purpose.

This subpart implements section 1905(a)(14) of the Act, which authorizes State plans to provide for inpatient hospital services, skilled nursing services, and intermediate care facility services for individuals age 65 or older in an institution for mental diseases, and sections 1902(a)(20)(B) and (C) and 1902(a)(21), which prescribe the conditions a State must meet to offer these services. (See § 431.620 of this subchapter for regulations implementing section 1902(a)(20)(A), which prescribe interagency requirements related to these services.)

§ 441.101 State plan requirements.

A State plan that includes Medicaid for individuals age 65 or older in institutions for mental diseases must provide that the requirements of this subpart are met.

§ 441.102 Plan of care for institutionalized recipients.

(a) The Medicaid agency must provide for a recorded individual plan of treatment and care to ensure that institutional care maintains the recipient at, or restores him to, the greatest possible degree of health and independent functioning.

(b) The plan must include—

(1) An initial review of the recipient's medical, psychiatric, and social needs—

(i) Within 90 days after approval of the State plan provision for services in institutions for mental disease; and

(ii) After that period, within 30 days after the date payments are initiated for services provided a recipient.

(2) Periodic review of the recipient's medical, psychiatric, and social needs;

(3) A determination, at least quarterly, of the recipient's need for continued institutional care and for alternative care arrangements;

(4) Appropriate medical treatment in the institution; and

(5) Appropriate social services.

§ 441.103 Alternate plans of care.

(a) The agency must develop alternate plans of care for each recipient age 65 or older who would otherwise need care in an institution for mental diseases.

(b) These alternate plans of care must—

(1) Make maximum use of available resources to meet the recipient's medical, social, and financial needs; and

(2) In Guam, Puerto Rico, and the Virgin Islands, make available appropriate social services authorized under sections 3(a)(4) (i) and (ii) or 1603(a)(4)(A) (i) and (ii) of the Act.

§ 441.105 Methods of administration.

The agency must have methods of administration to ensure that its responsibilities under this subpart are met.

§ 441.106 Comprehensive mental health program.

(a) If the plan includes services in public institutions for mental diseases, the agency must show that the State is making satisfactory progress in developing and implementing a comprehensive mental health program.

(b) The program must—

(1) Cover all ages;

(2) Use mental health and public welfare resources; including—

(i) Community mental health centers;

(ii) Nursing homes; and

(iii) Other alternatives to public institutional care; and

(3) Include joint planning with State authorities.

(c) The agency must submit annual progress reports within 3 months after the end of each fiscal year in which Medicaid is provided under this subpart.

Subpart D—Inpatient Psychiatric Services for Individuals Under Age 21 in Psychiatric Facilities or Programs

§ 441.150 Basis and purpose.

This subpart specifies requirements applicable if a State provides inpatient psychiatric services to individuals under age 21, as defined in § 440.160 of this subchapter and authorized under section 1905 (a)(16) and (h) of the Act.

§ 441.151 General requirements.

Inpatient psychiatric services for recipients under age 21 must be provided—

(a) Under the direction of a physician;

(b) By a psychiatric facility or an inpatient program in a psychiatric facility, either of which is accredited by the Joint Commission on Accreditation of Hospitals; and

(c) Before the recipient reaches age 21 or, if the recipient was receiving the services immediately before he reached age 21, before the earlier of the following—

(1) The date he no longer requires the services; or

(2) The date he reaches age 22.

§ 441.152 Certification of need for services.

(a) A team specified in § 441.154 must certify that—

(1) Ambulatory care resources available in the community do not meet the treatment needs of the recipient;

(2) Proper treatment of the recipient's psychiatric condition requires services on an inpatient basis under the direction of a physician; and

(3) The services can reasonably be expected to improve the recipient's condition or prevent further regression so that the services will no longer be needed.

(b) The certification specified in this section and in § 441.153 satisfies the utilization control requirement for physician certification in §§ 456.60, 456.160, 456.260, and 456.360 of this subchapter.

§ 441.153 Team certifying need for services.

Certification under § 441.152 must be made by terms specified as follows:

(a) For an individual who is a recipient when admitted to a facility or program, certification must be made by an independent team that—

(1) Includes a physician;

(2) Has competence in diagnosis and treatment of mental illness, preferably in child psychiatry; and

(3) Has knowledge of the individual's situation.

(b) For an individual who applies for Medicaid while in the facility of program, the certification must be—

(1) Made by the team responsible for the plan of care as specified in § 441.156; and

(2) Cover any period before application for which claims are made.

(c) For emergency admissions, the certification must be made by the team responsible for the plan of care (§ 441.156) within 14 days after admission.

§ 441.154 Active treatment.

Inpatient psychiatric services must involve "active treatment", which means implementation of a professionally developed and supervised individual plan of care, described in § 441.155 that is—

(a) Developed and implemented no later than 14 days after admission; and

(b) Designed to achieve the recipient's discharge from inpatient status at the earliest possible time.

§ 441.155 Individual plan of care.

(a) "Individual plan of care" means a written plan developed for each recipient in accordance with §§ 456.180-456.181, and 456.280-456.281 of this subchapter, to improve his condition to the extent that inpatient care is no longer necessary.

(b) The plan of care must—

(1) Be based on a diagnostic evaluation that includes examination of the medical, psychological, social, behavioral and developmental aspects of the recipient's situation and reflects the need for inpatient psychiatric care;

(2) Be developed by a team of professionals specified under § 441.156 in consultation with the recipient; and his parents, legal guardians, or others in whose care he will be released after discharge;

(3) State treatment objectives;

(4) Prescribe an integrated program of therapies, activities, and experiences designed to meet the objectives; and

(5) Include, at an appropriate time, post-discharge plans and coordination of inpatient services with partial discharge plans and related community services to ensure continuity of care with the recipient's family, school, and community upon discharge.

(c) The plan must be reviewed every 30 days by the team specified in § 441.156 to—

(1) Determine that services being provided are or were required on an inpatient basis, and

(2) Recommend changes in the plan as indicated by the recipient's overall adjustment as an inpatient.

(d) The development and review of the plan of care as specified in this section satisfies the utilization control requirements for—

(1) Recertification under §§ 456.60(b), 456.160(b), 456.260(b), and 456.360(b) of this subchapter; and

(2) Establishment and periodic review of the plan of care under §§ 456.80, 456.180, 456.280, and 456.380 of this subchapter.

[43 FR 45229, Sept. 29, 1978, as amended at 46 FR 48560, Oct. 1, 1981]

§ 441.156 Team developing individual plan of care.

(a) The individual plan of care under § 441.155 must be developed by an interdisciplinary team of physicians and other personnel who are employed by, or provide services to patients in, the facility.

(b) Based on education and experience, preferably including competence in child psychiatry, the team must be capable of—

(1) Assessing the recipient's immediate and long-range therapeutic needs, developmental priorities, and personal strengths and liabilities;

(2) Assessing the potential resources of the recipient's family;

(3) Setting treatment objectives; and

(4) Prescribing therapeutic modalities to achieve the plan's objectives.

(c) The team must include, as a minimum, either—

(1) A Board-eligible or Board-certified psychiatrist;

(2) A clinical psychologist who has a doctoral degree and a physician licensed to practice medicine or osteopathy; or

(3) A physician licensed to practice medicine or osteopathy with specialized training and experience in the diagnosis and treatment of mental diseases, and a psychologist who has a master's degree in clinical psychology

or who has been certified by the State or by the State psychological association.

(d) The team must also include one of the following:

(1) A psychiatric social worker.

(2) A registered nurse with specialized training or one year's experience in treating mentally ill individuals.

(3) An occupational therapist who is licensed, if required by the State, and who has specialized training or one year of experience in treating mentally ill individuals.

(4) A psychologist who has a master's degree in clinical psychology or who has been certified by the State or by the State psychological association.

§ 441.180 Maintenance of effort: General rule.

FFP is available only if the State maintains fiscal effort as prescribed under this subpart.

§ 441.181 Maintenance of effort: Explanation of terms and requirements.

(a) For purposes of § 441.182:

(1) The base year is the 4-quarter period ending December 31, 1971.

(2) Quarterly per capita non-Federal expenditures are expenditures for inpatient psychiatric services determined by reimbursement principles under Medicare. (See Part 405, Subpart D.)

(3) The number of individuals receiving inpatient psychiatric services in the current quarter means—

(i) The number of individuals receiving services for the full quarter; plus

(ii) The full quarter composite number of individuals receiving services for less than a full quarter.

(4) In determining the per capita expenditures for the base year, the Medicaid agency must compute the number of individuals receiving services in a manner similar to that in paragraph (a)(3) of this section.

(5) Non-Federal expenditures means the total amount of funds expended by the State and its political subdivisions, excluding Federal funds received directly or indirectly from any source.

(6) Expenditures for the current calendar quarter exclude Federal funds received directly or indirectly from any source.

(b) As a basis for determining the correct amount of Federal payments, each State must submit estimated and actual cost data and other information necessary for this purpose in the form and at the times specified in this subchapter and by HCFA guidelines.

(c) The agency must have on file adequate records to substantiate compliance with the requirements of § 441.182 and to ensure that all necessary adjustments have been made.

(d) Facilities that did not meet the requirements of §§ 441.151-441.156 in the base year, but are providing inpatient psychiatric services under those sections in the current quarter, must be included in the maintenance of effort computation if, during the base year, they were—

(1) Providing inpatient psychiatric services for individuals under age 21; and

(2) Receiving State aid.

§ 441.182 Maintenance of effort: Computation.

(a) For expenditures for inpatient psychiatric services for individuals under age 21, in any calendar quarter, FFP is available only to the extent that the total State Medicaid expenditures in the current quarter for inpatient psychiatric services and outpatient psychiatric treatment for individuals under age 21 exceed the sum of the following:

(1) The total number of individuals receiving inpatient psychiatric services in the current quarter times the average quarterly per capita non-Federal expenditures for the base year; and

(2) The average non-Federal quarterly expenditures for the base year for outpatient psychiatric services for individuals under age 21.

(b) FFP is available for 100 percent of the increase in expenditures over the base year period, but may not exceed the Federal medical assistance percentage times the expenditures under this subpart for inpatient psychiatric services for individuals under age 21.

Subpart E—Abortions

§ 441.200 Basis and purpose.

This subpart implements section 402 of Pub. L. 97-12, and subsequent laws that appropriate funds for the Medicaid program, including section 204 of Pub. L. 98-619. All of these laws prohibit the use of Federal funds to pay for abortions except when continuation of the pregnancy would endanger the mother's life.

[52 FR 47935, Dec. 17, 1987]

§ 441.201 Definition.

As used in this subpart, "physician" means a doctor of medicine or osteopathy who is licensed to practice in the State.

[52 FR 47935, Dec. 17, 1987]

§ 441.202 General rule.

FFP is not available in expenditures for an abortion unless the conditions specified in §§ 441.203 and 441.206 are met.

[52 FR 47935, Dec. 17, 1987]

§ 441.203 Life of the mother would be endangered.

FFP is available in expenditures for an abortion when a physician has found, and certified in writing to the Medicaid agency, that on the basis of his professional judgment, the life of the mother would be endangered if the fetus were carried to term. The certification must contain the name and address of the patient.

§§ 441.204—441.205 [Reserved]

§ 441.206 Documentation needed by the Medicaid agency.

FFP is not available in any expenditures for abortions or other medical procedures otherwise provided for under § 441.203 if the Medicaid agency has paid without first having received the certifications and documentation specified in that section.

[52 FR 47935, Dec. 17, 1987]

§ 441.207 Drugs and devices and termination of ectopic pregnancies.

FFP is available in expenditures for drugs or devices to prevent implantation of the fertilized ovum and for medical procedures necessary for the termination of an ectopic pregnancy.

§ 441.208 Recordkeeping requirements.

Medicaid agencies must maintain copies of the certifications and documentation specified in § 441.203 for 3 years under the recordkeeping requirements at 45 CFR 74.20.

[52 FR 47935, Dec. 17, 1987]

Subpart F—Sterilizations

SOURCE: 43 FR 52171, Nov. 8, 1978, unless otherwise noted.

§ 441.250 Applicability.

This subpart applies to sterilizations and hysterectomies reimbursed under Medicaid.

§ 441.251 Definitions.

As used in this subpart:

Hysterectomy means a medical procedure or operation for the purpose of removing the uterus.

Institutionalized individual means an individual who is (a) involuntarily confined or detained, under a civil or criminal statute, in a correctional or rehabilitative facility, including a mental hospital or other facility for the care and treatment of mental illness; or (b) confined, under a voluntary commitment, in a mental hospital or other facility for the care and treatment of mental illness.

Mentally incompetent individual means an individual who has been declared mentally incompetent by a Federal, State, or local court of competent jurisdiction for any purpose, unless the individual has been declared competent for purposes which include the ability to consent to sterilization.

Sterilization means any medical procedure, treatment, or operation for the purpose of rendering an individual permanently incapable of reproducing.

§ 441.252 State plan requirements.

A State plan must provide that the Medicaid agency will make payment under the plan for sterilization procedures and hysterectomies only if all the requirements of this subpart were met.

§ 441.253 Sterilization of a mentally competent individual aged 21 or older.

FFP is available in expenditures for the sterilization of an individual only if—

(a) The individual is at least 21 years old at the time consent is obtained;

(b) The individual is not a mentally incompetent individual;

(c) The individual has voluntarily given informed consent in accordance with all the requirements precribed in §§ 441.257 and 441.258; and

(d) At least 30 days, but not more than 180 days, have passed between the date of informed consent and the date of the sterilization, except in the case of premature delivery or emergency abdominal surgery. An individual may consent to be sterilized at the time of a premature delivery or emergency abdominal surgery, if at least 72 hours have passed since he or she gave informed consent for the sterilization. In the case of premature delivery, the informed consent must have been given at least 30 days before the expected date of delivery.

§ 441.254 Mentally incompetent or institutionalized individuals.

FFP is not available for the sterilization of a mentally incompetent or institutionalized individual.

§ 441.255 Sterilization by hysterectomy.

(a) FFP is not available in expenditures for a hysterectomy if—

(1) It was performed solely for the purpose of rendering an individual permanently incapable of reproducing; or

(2) If there was more than one purpose to the procedure, it would not have been performed but for the purpose of rendering the individual permanently incapable of reproducing.

(b) FFP is available in expenditures for a hysterectomy not covered by paragraph (a) of this section only under the conditions specified in paragraph (c), (d), or (e) of this section.

(c) FFP is available if—

(1) The person who secured authorization to perform the hysterectomy has informed the individual and her representative, if any, orally and in writing, that the hysterectomy will make the individual permanently incapable of reproducing; and

(2) The individual or her representative, if any, has signed a written acknowledgment of receipt of that information.

(d) Effective on March 8, 1979 or any date thereafter through the date of publication of these regulations at the option of the State, FFP is available if—

(1) The individual—

(i) Was already sterile before the hysterectomy; or

(ii) Requires a hysterectomy because of a life-threatening emergency situation in which the physician determines that prior acknowledgment is not possible; and

(2) The physician who performs the hysterectomy—

(i) Certifies in writing that the individual was already sterile at the time of the hysterectomy, and states the cause of the sterility; or

(ii) Certifies in writing that the hysterectomy was performed under a life-threatening emergency situation in which he or she determined prior acknowledgment was not possible. He or she must also include a description of the nature of the emergency.

(e) Effective March 8, 1979, or any date thereafter through the date of publication of these regulations at the option of the State, FFP is available for hysterectomies performed during a period of an individual's retroactive Medicaid eligibility if the physician who performed the hysterectomy certifies in writing that—

(1) The individual was informed before the operation that the hysterectomy would make her permanently incapable of reproducing; or

(2) One of the conditions in paragraph (d)(1) of this section was met. The physician must supply the information specified in paragraph (d)(2) of this section.

[47 FR 33702, Aug. 4, 1982]

§ 441.256 Additional condition for Federal financial participation (FFP).

(a) FFP is not available in expenditures for any sterilization or hysterectomy unless the Medicaid agency, before making payment, obtained documentation showing that the requirements of this subpart were met. This documentation must include a consent from, an acknowledgement of receipt of hysterectomy information or a physician's certification under § 441.255(d)(2), as applicable.

(b) With regard to the requirements of § 441.255(d) for hysterectomies performed from March 8, 1979 through November 2, 1982, FFP is available in expenditures for those services if the documentation showing that the requirements of that paragraph were met is obtained by the Medicaid agency before submitting a claim for FFP for that procedure.

[47 FR 33702, Aug. 4, 1982]

§ 441.257 Informed consent.

(a) *Informing the individual.* For purposes of this subpart, an individual has given informed consent only if—

(1) The person who obtained consent for the sterilization procedure offered to answer any questions the individual to be sterilized may have concerning the procedure, provided a copy of the consent form and provided orally all of the following information or advice to the individual to be sterilized:

(i) Advice that the individual is free to withhold or withdraw consent to the procedure at any time before the sterilization without affecting the right to future care or treatment and without loss or withdrawal of any federally funded program benefits to which the individual might be otherwise entitled.

(ii) A description of available alternative methods of family planning and birth control.

(iii) Advice that the sterilization procedure is considered to be irreversible.

(iv) A thorough explanation of the specific sterilization procedure to be performed.

(v) A full description of the discomforts and risks that may accompany or follow the performing of the procedure, including an explanation of the type and possible effects of any anesthetic to be used.

(vi) A full description of the benefits or advantages that may be expected as a result of the sterilization.

(vii) Advice that the sterilization will not be performed for at least 30 days, except under the circumstances specified in § 441.253(c).

(2) Suitable arrangements were made to insure that the information specified in paragraph (a)(1) of this section was effectively communicated to any individual who is blind, deaf, or otherwise handicapped;

(3) An interpreter was provided if the individual to be sterilized did not understand the language used on the consent form or the language used by the person obtaining consent;

(4) The individual to be sterilized was permitted to have a witness of his or her choice present when consent was obtained;

(5) The consent form requirements of § 441.258 were met; and

(6) Any additional requirement of State or local law for obtaining consent, except a requirement for spousal consent, was followed.

(b) *When informed consent may not be obtained.* Informed consent may not be obtained while the individual to be sterilized is—

(1) In labor or childbirth;

(2) Seeking to obtain or obtaining an abortion; or

(3) Under the influence of alcohol or other substances that affect the individual's state of awareness.

§ 441.258 Consent form requirements.

(a) *Content of consent form.* The consent form must be a copy of the form appended to this subpart or another form approved by the Secretary.

(b) *Required signatures.* The consent form must be signed and dated by—

(1) The individual to be sterilized;

(2) The interpreter, if one was provided;

(3) The person who obtained the consent; and

(4) The physician who performed the sterilization procedure.

(c) *Required certifications.* (1) The person securing the consent must certify, by signing the consent form, that

(i) Before the individual to be sterilized signed the consent form, he or she advised the individual to be sterilized that no Federal benefits may be withdrawn because of the decision not to be sterilized;

(ii) He or she explained orally the requirements for informed consent as set forth on the consent form; and

(iii) To the best of his or her knowledge and belief, the individual to be sterilized appeared mentally competent and knowingly and voluntarily consented to be sterilized.

(2) The physician performing the sterilization must certify, by signing the consent form, that:

(i) Shortly before the performance of sterilization, he or she advised the individual to be sterilized that no Federal benefits may be withdrawn because of the decision not to be sterilized;

(ii) He or she explained orally the requirements for informed consent as set forth on the consent form; and

(iii) To the best of his or her knowledge and belief, the individual appeared mentally competent and knowingly and voluntarily consented to be sterilized.

Except in the case of premature delivery or emergency abdominal surgery, the physician must further certify that at least 30 days have passed between the date of the individual's signature on the consent form and the date upon which the sterilization was performed.

(3) In the case of premature delivery or emergency abdominal surgery performed within 30 days of consent, the physician must certify that the sterilization was performed less than 30 days, but not less than 72 hours after informed consent was obtained because of premature delivery or emergency abdominal surgery and—

(i) In the case of premature delivery, must state the expected date of delivery; or

(ii) In the case of abdominal surgery, must describe the emergency.

(4) If an interpreter is provided, the interpreter must certify that he or she translated the information and advice presented orally and read the consent form and explained its contents to the individual to be sterilized and that, to the best of the interpreter's knowledge and belief, the individual understood what the interpreter told him or her.

§ 441.259 Review of regulations.

The Secretary will request public comment on the operation of this subpart not later than 3 years after its effective date.

APPENDIX TO SUBPART F—REQUIRED CONSENT FORM

NOTICE: Your decision at any time not to be sterilized will not result in the withdrawal or withholding of any benefits provided by programs or projects receiving Federal funds.

CONSENT TO STERILIZATION

I have asked for and received information about sterilization from (doctor or clinic). When I first asked for the information, I was told that the decision to be sterilized is completely up to me. I was told that I could decide not to be sterilized. If I decide not to be sterilized, my decision will not affect my right to future care or treatment. I will not lose any help or benefits from programs receiving Federal funds, such as A.F.D.C. or Medicaid that I am now getting or for which I may become eligible.

I understand that the sterilization must be considered permanent and not reversible. I have decided that I do not want to become pregnant, bear children or father children.

I was told about those temporary methods of birth control that are available and could be provided to me which will allow me to bear or father a child in the future. I have rejected these alternatives and chosen to be sterilized.

I understand that I will be sterilized by an operation known as a ————. The discomforts, risks and benefits associated with the operation have been explained to me. All my questions have been answered to my satisfaction.

I understand that the operation will not be done until at least 30 days after I sign this form. I understand that I can change my mind at any time and that my decision at any time not to be sterilized will not result in the withholding of any benefits or medical services provided by Federally funded programs.

I am at least 21 years of age and was born on (Day) (Month) (Year).

I, ————, hereby consent of my own free will to be sterilized by ———— by a method called ————. My consent expires 180 days from the date of my signature below.

I also consent to the release of this form and other medical records about the operation to:

Representatives of the Department of Health and Human Services or

Employees of programs or projects funded by that Department but only for determining if Federal laws were observed.

I have received a copy of this form. (Signature) (Date) (Month) (Day) (Year).

You are requested to supply the following information, but it is not required: (Race and ethnicity designation (please check)) Black (not of Hispanic origin); Hispanic; Asian or Pacific Islander; American Indian or Alaskan native; or White (not of Hispanic origin).

INTERPRETER'S STATEMENT

If an interpreter is provided to assist the individual to be sterilized:

I have translated the information and advice presented orally to the individual to be sterilized by the person obtaining this consent. I have also read him/her the consent form in ———— ———— language and explained its contents to him/her. To the best of my knowledge and belief he/she understood this explanation. (Interpreter) (Date).

STATEMENT OF PERSON OBTAINING CONSENT

Before (name of individual) signed the consent form, I explained to him/her the nature of the sterilization operation ————, the fact that it is intended to be a final and irreversible procedure and the discomforts, risks and benefits associated with it.

I counseled the individual to be sterilized that alternative methods of birth control are available which are temporary. I explained that sterilization is different because it is permanent.

I informed the individual to be sterilized that his/her consent can be withdrawn at any time and that he/she will not lose any health services or any benefits provided by Federal funds.

To the best of my knowledge and belief the individual to be sterilized is at least 21 years old and appears mentally competent. He/She knowingly and voluntarily requested to be sterilized and appears to understand the nature and consequence of the procedure. (Signature of person obtaining consent) (Date) (Facility) (Address).

PHYSICIAN'S STATEMENT

Shortly before I performed a sterilization operation upon (Name of individual to be sterilized) on (Date of sterilization) (operation), I explained to him/her the nature of the sterilization operation (specify type of operation), the fact that it is intended to be a final and irreversible procedure and the discomforts, risks and benefits associated with it.

I counseled the individual to be sterilized that alternative methods of birth control are available which are temporary. I explained that sterilization is different because it is permanent.

I informed the individual to be sterilized that his/her consent can be withdrawn at any time and that he/she will not lose any health services or benefits provided by Federal funds.

To the best of my knowledge and belief the individual to be sterilized is at least 21 years old and appears mentally competent. He/She knowingly and voluntarily requested to be sterilized and appeared to understand the nature and consequences of the procedure.

(*Instructions for use of alternative final paragraphs:* Use the first paragraph below except in the case of premature delivery or emergency abdominal surgery where the sterilization is performed less than 30 days after the date of the individual's signature on the consent form. In those cases, the second paragraph below must be used. Cross out the paragraph which is not used.)

(1) At least 30 days have passed between the date of the individual's signature on this consent form and the date the sterilization was performed.

(2) This sterilization was performed less than 30 days but more than 72 hours after the date of the individual's signature on this consent form because of the following circumstances (check applicable box and fill in information requested): Premature delivery.

Individual's expected date of delivery:————

☐ Emergency abdominal surgery: (describe circumstances):————(Physician) (Date).

Subpart G—Home and Community-Based Services: Waiver Requirements

SOURCE: 46 FR 48541, Oct. 1, 1981, unless otherwise noted.

§ 441.300 Basis and purpose.

Section 1915(c) of the Act permits States to offer, under a waiver of statutory requirements, an array of home and community-based services that an individual needs to avoid institutionalization. Those services are defined in § 440.180 of this subchapter. This subpart describes what the Medicaid agency must do to obtain a waiver.

§ 441.301 Contents of request for a waiver.

(a) A request for a waiver under this section must consist of—

(1) The assurances required by § 441.302 and the supporting documentation required by § 441.303;

(2) When applicable, requests for waivers of the requirements of section 1902(a) (1) or (10) of the Act; and

(3) A statement as to whether the agency will refuse to offer home or community-based services to any recipient because it can reasonably expect that the cost of the home or community-based services furnished to that recipient would exceed the cost of the level of care provided in an SNF or ICF (or ICF/MR if applicable).

(b) If the agency furnishes home and community-based services, as defined in § 440.180 of this subchapter, under a waiver granted under this subpart, the waiver request must—

(1) Provide that the services are furnished—

(i) Under a written plan of care subject to approval by the Medicaid agency;

(ii) Only to recipients who are not inpatients of a hospital, SNF, ICF, or ICF/MR, and who the agency determines would require the level of care provided in an SNF or ICF (or ICF/MR, if applicable) under Medicaid (as defined in §§ 440.40 and 440.150) if not furnished these services;

(2) Describe the qualifications of the individual or individuals who will be responsible for developing the individual plan of care;

(3) Describe the group or groups of individuals to whom the services will be offered;

(4) Describe the services to be furnished;

(5) Provide that the documentation requirements regarding individual evaluation, specified in § 441.303(c), will be met; and

(6) Be limited to one of the following target groups or any subgroup thereof that the State may define:

(i) Aged or disabled, or both.

(ii) Mentally retarded or developmentally disabled, or both.

(iii) Mentally ill.

[46 FR 48541, Oct. 1, 1981, as amended at 50 FR 10026, Mar. 13, 1985]

§ 441.302 State assurances.

HCFA will not grant a waiver under this subpart and may terminate a waiver unless the Medicaid agency provides the following satisfactory assurances to HCFA:

(a) *Health and Welfare*—Assurance that necessary safeguards have been taken to protect the health and welfare of the recipients of the services. Those safeguards must include—

(1) Adequate standards for all types of providers that provide services under the waiver;

(2) Assurance that the standards of any State licensure or certification requirements are met for services or for individuals furnishing services that are provided under the waiver; and

(3) Assurance that all facilities covered by section 1616(e) of the Act, in which home and community-based services will be provided, are in compliance with applicable State standards that meet the requirements of 45 CFR Part 1397 for board and care facilities.

(b) *Financial accountability.*—The agency will assure financial accountability for funds expended for home and community-based services, provide for an independent audit of its waiver program (except as HCFA may otherwise specify for particular waivers), and it will maintain and make available to HHS, the Comptroller General, or other designees, appropriate financial records documenting the cost of services provided under the waiver, including reports of any independent audits conducted.

(c) *Evaluation of need.*—Assurance that the agency will provide for an evaluation (and periodic reevaluations) of the need for the level of care provided in an SNF, ICF, or ICF/MR, as defined by §§ 440.40 and 440.150, respectively, when there is a reasonable indication that individuals might need such services in the near future but for the availability of home and community-based services.

(d) *Alternatives*—Assurance that when a recipient is determined to be likely to require the level of care provided in an SNF, ICF, or ICF/MR, the recipient or his or her legal representative will be—

(1) Informed of any feasible alternatives available under the waiver; and

(2) Given the choice of either institutional or home and community-based services.

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(e) *Expenditures.* Assurance that—(1) The average per capita fiscal year expenditures under the waiver will not exceed the average per capita expenditures for the level of care provided in an SNF, ICF, or ICF/MR under the State plan that would have been made in that fiscal year had the waiver not been granted. (i) These expenditures must be reasonably estimated by the agency; and (ii) The estimates must be annualized and must cover each year of the waiver period.

(2) The agency's actual total expenditures for home and community-based services under the waiver and its claim for FFP in expenditures for the services will not exceed the agency's approved estimates for these services, expressed as the product of (C×D) in the supporting documentation required under § 441.303(f), for each year of the waiver period.

(3) The agency's actual total expenditures for home and community-based and other Medicaid services provided to individuals under the waiver will not, in any year of the waiver period, exceed the amount that would be incurred by Medicaid for these individuals in an SNF, ICF, or ICF/MR, in the absence of a waiver.

(f) *Reporting.* Assurance that annually, the agency will provide HCFA with information on the waiver's impact. The information must be consistent with a data collection plan designed by HCFA and must address the waiver's impact on—

(1) The type, amount, and cost of services provided under the State plan; and

(2) The health and welfare of recipients.

[50 FR 10026, Mar. 13, 1985]

§ 441.303 Supporting documentation required.

The agency must furnish HCFA with sufficient information to support the assurances required by § 441.302. Except as HCFA may otherwise specify for particular waivers, the information must consist of the following, at a minimum:

(a) A description of the safeguards necessary to protect the health and welfare of recipients. This information must include a copy of the standards established by the State for facilities that are covered by section 1616(e) of the Act.

(b) A description of the records and information that will be maintained to support financial accountability.

(c) A description of the agency's plan for the evaluation and reevaluation of recipients, including—(1) A description of who will make these evaluations and how they will be made; (2) A copy of the evaluation instrument to be used; (3) The agency's procedure to ensure the maintenance of written documentation on all evaluations and reevaluations; and (4) The agency's procedure to ensure reevaluations of need at regular intervals.

(d) A description of the agency's plan for informing eligible recipients of the feasible alternatives available under the waiver and allowing recipients to choose either institutional services or home and community-based services.

(e) An explanation of how the agency will apply the applicable provisions regarding the post-eligibility treatment of income and resources of those individuals receiving home and community-based services who are eligible under a special income level (included in § 435.217 of this chapter).

(f) An explanation with supporting documentation satisfactory to HCFA of how the agency estimated the per capita expenditures for services. This information must include but is not limited to the estimated utilization rates and costs for services included in the plan, the number of actual and projected beds in Medicaid certified SNFs, ICFs, and ICF/MRs by type, and evidence of the need for additional bed capacity in the absence of the waiver.

(1) The annual average per capita expenditure estimate of the cost of home and community-based and other Medicaid services under the waiver must not exceed the annual average per capita expenditures of the cost of services in the absence of a waiver. The estimates are to be based on the following equation:

$$\frac{(A\times B)+(A'\times B')+(C\times D)+(C'\times D')+(HxI)}{F+H} \leq \frac{(F\times G)+(H\times I)+(F'\times G')}{F+H}$$

where:

A = the estimated annual number of beneficiaries who would receive the level of care provided in an SNF, ICF, or ICF/MR with the waiver.

B = the estimated annual Medicaid expenditure for SNF, ICF, or ICF/MR care per eligible Medicaid user with the waiver.

C = the estimated annual number of beneficiaries who would receive home and community-based services under the waiver.

D = the estimated annual Medicaid expenditure for home and community-based services per eligible Medicaid user.

F = the estimated annual number of beneficiaries who would likely receive the level of care provided in an SNF, ICF, or ICF/MR in the absence of the waiver.

G = the estimated annual Medicaid expenditure per eligible Medicaid user of such institutional care in the absence of the waiver.

H = the estimated annual number of beneficiaries who would receive any of the noninstitutional, long-term care services otherwise provided under the State plan as an alternative to institutional care.

I = the estimated annual Medicaid expenditure per eligible Medicaid user of the noninstitutional services referred to in H.

The symbol "≤" is intended to mean that the result of the left side of the equation must be less than or *equal to* the result of the right side of the equation.

A' = the estimated annual number of beneficiaries referred to in A who would receive any of the acute care services otherwise provided under the State plan.

B' = the estimated annual Medicaid expenditure per eligible Medicaid user of the acute care services referred to in A'.

C' = the estimated annual number of beneficiaries referred to in C who would receive any of the acute care services otherwise provided under the State plan.

D' = the estimated annual Medicaid expenditure per eligible Medicaid user of the acute care services referred to in C'.

F' = the estimated annual number of beneficiaries referred to in F who would receive any of the acute care services otherwise provided under the State plan.

G' = the estimated annual Medicaid expenditure per eligible Medicaid user of the acute care services referred to in F'.

(2) For purposes of the equation, acute care services means all services otherwise provided under the State plan that are neither SNF, ICF, or ICF/MR services, nor the noninstitutional, long-term care services referred to in H.

(3) Data on the estimated annual number of beneficiaries and expenditures for those who would otherwise receive an SNF, ICF, or ICF/MR level of care is required for all three types of institutions only if the waiver request provides that each of these groups will be offered home and community-based services. For example, if the request does not include persons who would otherwise receive an ICF/MR level of care, the State is not required to furnish data on that group.

(4) The data must show the estimated annual number of beneficiaries who will be deinstitutionalized from certified SNFs, ICFs and ICF/MRs because they would receive home and community-based services under the waiver, and the estimated annual number of beneficiaries whose admission to such institutions would be diverted or deflected because of the waiver services. For the latter group, the State's evaluation process required by § 441.303(c) must provide for a more detailed description of their evaluation and screening procedures for recipients to assure that waiver services will be limited to persons who would otherwise receive the level of care provided in an SNF, ICF, or ICF/MR.

(g) Except as HCFA may otherwise specify for particular waivers, the agency must provide for an independent assessment of its waiver that evaluates the quality of care provided, access to care, and cost-effectiveness. The results of the assessment must be submitted to HCFA at least 90 days prior to the third anniversary of the approved waiver period and cover at least the first 24 months of the waiver.

[46 FR 48532, Oct. 1, 1981, as amended at 50 FR 10027, Mar. 13, 1985; 50 FR 25080, June 17, 1985]

§ 441.304 Duration of a waiver.

(a) The effective date for a waiver of Medicaid requirements to provide home and community-based services approved under this subpart is established by HCFA prospectively on or after the date of approval and after consultation with the State agency. The waiver continues for a three-year period from the effective date. If the agency requests it, the waiver may be extended for additional three-year periods, if HCFA's review of the prior three-year period shows that the assurances required by § 441.302 of this subpart were met.

(b) HCFA will determine whether a request for extension of an existing waiver is actually an extension request or a request for a new waiver.

(1) Generally, if a State's extension request proposes a change in services provided, eligible population, service area, or statutory sections waived, HCFA will consider it a new waiver request.

(2) If a State submits an extension request that would add a new group to the existing group of beneficiaries covered under the waiver, HCFA will consider it to be two requests; one as an extension request for the existing group, and the other as a new waiver request for the new group.

(c) HCFA *may* grant a State an extension of its existing waiver for up to 90 days to permit the State to document more fully the satisfaction of statutory and regulatory requirements needed to approve a new waiver request. HCFA will consider this option when it requests additional information on a new waiver request submitted by a State to extend its existing waiver or when HCFA disapproves a State's request for extension.

(d) If HCFA finds that an agency is not meeting any of the requirements for a waiver contained in this subpart, the agency will be given a notice of HCFA's findings and an opportunity for a hearing to rebut the findings. If HCFA determines that the agency is not in compliance with this subpart after the notice and any hearing, HCFA may terminate the waiver. For example:

(1) If HCFA finds that the agency's actual total expenditures for home and community-based services under the waiver exceed the agency's approved estimates for these services, expressed as the product of ($C \times D$) in the supporting documentation required under § 441.303(f), for any year of the waiver period, the waiver may be terminated; or

(2) The waiver may be terminated if HCFA finds that the agency's actual total expenditures for home and community-based and other Medicaid services provided to individuals under the waiver exceed, for any year of the waiver period, the amount that would be incurred by Medicaid for these individuals in an SNF, ICF, or ICF/MR, in the absence of a waiver.

[50 FR 10028, Mar. 13, 1985; 50 FR 25080, June 17, 1985]

§ 441.305 Notification of a waiver termination.

(a) If a State chooses to terminate its waiver before the three-year period is up, it must notify HCFA in writing 30 days before terminating services to recipients.

(b) If HCFA or the State terminates the waiver, the State must notify recipients of services under the waiver in accordance with § 431.210 of this subchapter and notify them 30 days before terminating services.

§ 441.306 Hearings procedures for waiver terminations.

The procedures specified in Subpart D of Part 430 of this chapter are applicable to State requests for hearings on terminations.

[50 FR 10028, Mar. 13, 1985]

§ 441.310 Limits on Federal financial participation (FFP).

(a) FFP for home and community-based services listed in § 440.180 of this chapter is not available in expenditures for—

(1) Services provided in a facility subject to the health and welfare requirements described in § 441.302(a) during any period in which the facility

is found not to be in compliance with the applicable State standards described in that section;

(2) Home and community-based services that exceed the agency's approved estimated total expenditures for these services, expressed as the product of (C × D) in the supporting documentation required under § 441.303(f) for each year of the waiver period; and

(3) The cost of room and board except when provided as part of respite care in a facility approved by the State that is not a private residence. For purposes of this provision, "board" means three meals a day or any other full nutritional regimen and does not include meals provided as part of a program of adult day health services.

(b) On or after June 11, 1985, the limits specified in paragraphs (a)(1) and (a)(2) of this section are applicable to all existing and future waiver programs under this part.

[50 FR 10028, Mar. 13, 1985]

PART 442—STANDARDS FOR PAYMENT FOR SKILLED NURSING AND INTERMEDIATE CARE FACILITY SERVICES

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Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302), unless otherwise noted.

Source: 43 FR 45233, Sept. 29, 1978, unless otherwise noted.

Subpart A—General Provisions

§ 442.1 Basis and purpose.

(a) This part states requirements for provider agreements and facility certification relating to the provision of services furnished by skilled nursing facilities and intermediate care facilities to Medicaid recipients. The requirements apply to State Medicaid agencies and survey agencies and to the facilities. This part is based on the following sections of the Act:

Section 1902(a)(4), administrative methods for proper and efficient operation of the State plan;
Section 1902(a)(27), provider agreements;
Section 1902(a)(28), skilled nursing facility standards;
Section 1902(a)(33)(B), State survey agency functions;
Section 1902(i), circumstances and procedures for denial of payment and termination of provider agreements in certain cases;
Section 1905 (c) and (d), definition of intermediate care facility services;
Section 1905 (f) and (i), definition of skilled nursing facility services;
Section 1910, certification and approval of SNFs and of RHCs;
Section 1913, hospital providers of skilled nursing and intermediate care services, and
Section 1919, correction and reduction plans for intermediate care facilities for the mentally retarded.

(b) Section 431.610 of this subchapter contains requirements for designating the State licensing agency to survey these facilities and for certain survey agency responsibilities.

[43 FR 45233, Sept. 29, 1978, as amended at 47 FR 31533, July 20, 1982; 51 FR 24490, July 3, 1986; 53 FR 1993, Jan. 25, 1988; 53 FR 20495, June 3, 1988]

Effective Date Note: At 53 FR 20495, June 3, 1988, §442.1(a), the first sentence was revised, effective October 3, 1988. For the convenience of the user, the superseded text is set forth below:

§ 442.1 Basis and purpose.

(a) This part states requirements for provider agreements, facility certification, and facility standards relating to the provision of services furnished by skilled nursing facilities and intermediate care facilities, including intermediate care facilities for the mentally retarded, to Medicaid recipients.

* * * * *

§ 442.2 Terms.

In this part—

Facility refers to a skilled nursing facility (SNF), an intermediate care facility (ICF), and an intermediate care facility for the mentally retarded or persons with related conditions (ICF/MR). Except where otherwise specified, "ICF" refers to both an ICF and an ICF/MR.

Facility, and any specific type of facility referred to, may include a distinct part of a facility as specified in § 440.40 or § 440.150 of this subchapter.

Immediate jeopardy or *immediate threat* for Medicaid certified facilities means a situation in which a facility's noncompliance with one or more conditions of participation (for SNFs) or standards (for ICFs and ICFs/MR) poses a serious threat to patients' or clients' health or safety such that immediate corrective action is necessary. There is no substantive difference between *immediate jeopardy* and *immediate threat.*

New admission means the admission of a Medicaid recipient who has never been in the facility or, if previously admitted, had been discharged or had voluntarily left the facility. The term does not include the following:

(a) Individuals who were in the facility before the effective date of denial of payment for new admissions, even if they become eligible for Medicaid after that date.

(b) If the approved State plan includes payments for reserved beds, individuals who, after a temporary absence from the facility, are readmitted to beds reserved for them in accordance with § 447.40(a) of this chapter.

[43 FR 45233, Sept. 29, 1978, as amended at 51 FR 24491, July 3, 1986; 53 FR 1993, Jan. 25, 1988]

Subpart B—Provider Agreements

§ 442.10 State plan requirement.

A State plan must provide that requirements of this subpart are met.

§ 442.12 Provider agreement: General requirements.

(a) *Certification and recertification.* Except as provided in paragraph (b) of this section, a Medicaid agency may not execute a provider agreement with a facility for SNF or ICF services nor make Medicaid payments to a facility for those services unless the Secretary or the State survey agency has certified the facility under this part to provide those services. (See § 442.101 for certification by the Secretary or by the State survey agency).

(b) *Exception.* The certification requirement of paragraph (a) of this section does not apply with respect to Christian Science sanitoria operated, or listed and certified, by the First Church of Christ Scientist, Boston, Mass.

(c) *Conformance with certification condition.* An agreement must be in accordance with the certification provisions set by the Secretary or the survey agency under Subpart C of this part.

(d) *Denial for good cause.* (1) If the Medicaid agency has adequate documentation showing good cause, it may refuse to execute an agreement, or may cancel an agreement, with a certified facility.

(2) A provider agreement is not a valid agreement for purposes of this part even though certified by the State survey agency, if the facility fails to meet the civil rights requirements set forth in 45 CFR Parts 80, 84, and 90.

[45 FR 22936, Apr. 4, 1980]

§ 442.13 Effective date of agreement.

(a) *Basic requirements.* If the Medicaid agency enters into a provider agreement, the effective date must be in accordance with this section.

(b) *All Federal requirements are met on the date of the survey.* The agreement must be effective on the date the onsite survey is completed (or on the day following the expiration of a current agreement) if, on the date of the survey, the provider meets:

(1) All Federal health and safety requirements; and

(2) Any other requirements imposed by the Medicaid agency.

(c) *All Federal requirements are not met on the date of the survey.* If the provider fails to meet any of the requirements specified in paragraph (b) of this section, the agreement must be effective on the earlier of the following dates:

(1) The date on which the provider meets all requirements.

(2) The date on which the provider is found to meet all applicable conditions of participation and submits a correction plan for other deficiencies to the State survey agency or an approvable waiver request, or both.

[45 FR 22936, Apr. 4, 1980; as amended at 53 FR 20495, June 3, 1988]

EFFECTIVE DATE NOTE: At 53 FR 20495, June 3, 1988, §442.13(b)(1), was amended by removing the word "standards" and adding in its place the word "requirements," and paragraph (c) was revised, effective October 3, 1988. For the convenience of the user, the superseded text is set forth below:

§ 442.13 Effective date of agreement.

* * * * *

(c) *All Federal requirements are not met on the date of the survey.* If the provider fails to meet any of the requirements specified in paragraph (b) of this section, the agreement must be effective on the earlier of the following dates:

(1) The date on which the provider meets all requirements.

(2) The date on which the provider submits a correction plan acceptable to the State survey agency or an approvable waiver request, or both.

§ 442.14 Effect of change of ownership.

(a) *Assignment of agreement.* When there is a change of ownership, the Medicaid agency must automatically assign the agreement to the new owner.

(b) *Conditions that apply to assigned agreements.* An assigned agreement is subject to all applicable statutes and regulations and to the terms and conditions under which it was originally issued, including, but not limited to, the following:

(1) Any existing plan of correction.

(2) Any expiration date.

(3) Compliance with applicable health and safety requirements.

(4) Compliance with the ownership and financial interest disclosure requirements of §§ 455.104 and 455.105 of this chapter.

(5) Compliance with civil rights requirements set forth in 45 CFR Parts 80, 84, and 90.

(6) Compliance with any additional requirements imposed by the Medicaid agency.

[45 FR 22936, Apr. 4, 1980, as amended at 53 FR 20495, June 3, 1988]

EFFECTIVE DATE NOTE: At 53 FR 20495, June 3, 1988, §442.14(b)(3), was amended by removing the word "standards" and adding in its place the word "requirements," effective October 3, 1988.

§ 442.15 Duration of agreement.

(a) Except as specified under § 442.16, the duration of an agreement may not exceed 12 months.

(b) The agreement must be for the same duration as the certification period set by the survey agency. However, if the Medicaid agency has adequate documentation showing good cause, it may make an agreement for less than this period.

(c) FFP is available for services provided by a facility for up to 30 days after its agreement expires or terminates under the conditions specified in § 441.11 of this subchapter.

(d) The limitation specified in paragraph (a) of this section does not apply to hospitals with a swing-bed approval.

[43 FR 45233, Sept. 29, 1978, as amended at 47 FR 31532, July 20, 1982]

§ 442.16 Extension of agreement.

A Medicaid agency may extend a provider agreement for a single period of up to 2 months beyond the original expiration date specified in the agreement if it receives written notice from the survey agency, before the expiration date of the agreement, that extension will not jeopardize the patients' health and safety, and—

(a) Is needed to prevent irreparable harm to the facility or hardship to the recipients in the facility; or

(b) Is needed because it is impracticable to determine, before the expiration date, whether the facility meets certification requirements.

[43 FR 45233, Sept. 29, 1978, as amended at 52 FR 32551, Aug. 28, 1987; 53 FR 20495, June 3, 1988]

EFFECTIVE DATE NOTE: At 53 FR 20495, June 3, 1988, §442.16(b), was amended by removing the word "standards" and adding in its place the word "requirements," effective October 3, 1988.

§ 442.20 Additional requirements for agreements with SNF's participating in Medicare.

(a) The Medicaid agency's agreement with a SNF participating in Medicare must—

(1) Provide for the same terms and conditions as Medicare certification; and

(2) Be for the same duration as the Medicare certification.

(b) If the Secretary notifies the Medicaid agency that he has denied, terminated, or refused to renew a Medicare agreement with a SNF, the agency must deny, terminate, or refuse to renew its Medicaid agreement with that SNF. The denial, termination, or refusal to renew the Medicaid agreement must be effective on the same date as the denial, termination, or refusal to renew the Medicare agreement.

(c) If the Medicaid agency has terminated an agreement under paragraph (b) of this section, it may not make another agreement with that SNF until—

(1) The conditions causing the termination are removed; and

(2) The SNF provides reasonable assurance to the survey agency that the conditions will not recur.

[43 FR 45233, Sept. 29, 1978, as amended at 44 FR 9753, Feb. 15, 1979]

§ 442.30 Agreement as evidence of certification.

(a) Under §§ 440.40(a) and 440.150 of this chapter, FFP is available in expenditures for SNF and ICF services only if the facility has been certified as meeting the requirements for Medicaid participation, as evidenced by a provider agreement executed under this part. An agreement is not valid evidence that a facility has met those requirements if HCFA determines that—

(1) The survey agency failed to apply the applicable certification requirements under Subpart D, E, or F of this part or Subpart D of Part 483, which sets forth the conditions of participation for ICFs/MR;

(2) The survey agency failed to follow the rules and procedures for certification set forth in Subpart C of this part and § 431.610 of this subchapter;

(3) The survey agency failed to perform any of the functions specified in § 431.610(g) of this subchapter relating to evaluating and acting on information about the facility and inspecting the facility;

(4) The survey agency failed to use the Federal standards, and the forms, methods and procedures prescribed by HCFA as required under § 431.610(f)(1) of this chapter, for determining the qualifications of providers; or

(5) The survey agency failed to adhere to the following principles in determining compliance:

(i) The survey process is the means to assess compliance with Federal health, safety and quality standards;

(ii) The survey process uses resident outcomes as the primary means to establish the compliance status of facilities. Specifically, surveyors will directly observe the actual provision of care and services to residents, and the effects of that care, to assess whether the care provided meets the needs of individual residents;

(iii) Surveyors are professionals who use their judgment, in concert with Federal forms and procedures, to determine compliance;

(iv) Federal procedures are used by all surveyors to ensure uniform and consistent application and interpretation of Federal requirements;

(v) Federal forms are used by all surveyors to ensure proper recording of findings and to document the basis for the findings.

(6) The survey agency failed to assess in a systematic manner a facility's actual provision of care and services to residents and effects of that care on residents.

(7) Required elements of the SNF or ICF survey process include all of the following:

(i) An entrance conference;

(ii) A resident-centered tour of facility;

(iii) An in-depth review of a sample of residents including observation, interview and record review;

(iv) Observation of the preparation and administration of drugs for a sample of residents;

(v) Evaluation of a facility's meals, dining areas and eating assistance procedures;

(vi) Formulation of a deficiency statement based on the incorporation of all appropriate findings onto the survey report form;

(vii) An exit conference; and

(viii) Follow-up surveys as appropriate.

(8) The agreement's terms and conditions do not meet the requirements of this subpart.

(b) The Administrator will make the determination under paragraph (a) of this section through onsite surveys, other Federal reviews, State certification records, or reports he may require from the Medicaid or survey agency.

(c) If the Administrator disallows a State's claim for FFP because of a determination under paragraph (a) of this section, the State is entitled upon request to reconsideration of the disallowance under 45 CFR Part 16.

[43 FR 45233, Sept. 29, 1978, as amended at 51 FR 21558, June 13, 1986; 53 FR 20495, June 3, 1988; 53 FR 23101, June 17, 1988]

EFFECTIVE DATE NOTE: At 53 FR 20495, June 3, 1988, §442.30 paragraph (a)(1) was revised, effective October 3, 1988. For the convenience of the user, the superseded text is set forth below:

§ 442.30 Agreement as evidence of certification.

(a) * * *

(1) The survey agency failed to apply the applicable certification standards required under Subpart D, E, F, or G of this part;

* * * * *

§ 442.40 Availability of FFP during appeals.

(a) *Definitions.* As used in this section—

Effective date of expiration means the date of expiration originally specified in the provider agreement, or the later date specified if the agreement is extended under § 442.16; and

Effective date of termination means a date earlier than the expiration date, set by the Medicaid agency when continuing participation until the expiration date is not justified, because the facility no longer meets the requirements for participation.

(b) *Scope, applicability, and effective date*—(1) *Scope.* This section sets forth the extent of FFP in State Medicaid payments to a SNF or ICF after its provider agreement has been terminated or has expired and not been renewed.

(2) *Applicability.* (i) This section and § 442.42 apply only when the Medicaid agency, of its own volition, terminates or does not renew a provider agreement, and only when the survey agency certifies that there is no jeopardy to recipient health and safety. When the survey agency certifies that there is jeopardy to recipient health and safety, or when it fails to certify that there is no jeopardy, FFP ends on the effective date of termination or expiration.

(ii) When the State acts under instructions from HCFA, FFP ends on the date specified by HCFA (HCFA instructs the State to terminate the Medicaid provider agreement when HCFA (A) terminates the Medicare provider agreement with a SNF, or, (B) in validating a State survey agency certification, determines that a SNF or ICF does not meet the requirements for participation.)

(3) *Effective date.* This section and § 442.42 apply to terminations or expirations that are effective on or after September 28, 1987. For terminations or nonrenewals that were effective before that date, FFP may continue for up to 120 days from September 28, 1987, or 12 months from the effective date of termination or nonrenewal, whichever is earlier.

(c) *Basic rules.* (1) Except as provided in paragraphs (d) and (e) of this section, FFP in payments to a SNF or ICF ends on the effective date of termination of the facility's provider agreement, or if the agreement is not terminated, on the effective date of expiration.

(2) If State law, or a Federal or State court order or injunction, requires the agency to extend the provider agreement or continue payments to a facility after the dates specified in paragraph (d) of this section, FFP is not available in those payments.

(d) *Exception: Continuation of FFP after termination or expiration of provider agreement*—(1) *Conditions for continuation.* FFP is available after the effective date of termination or expiration only if—

(i) The evidentiary hearing required under § 431.153 of this chapter is provided by the State agency after the effective date of termination or expiration (or, if begun before termination or expiration, is not completed until after that date); and

(ii) Termination or nonrenewal action is based on a survey agency certification that there is no jeopardy to recipients' health and safety.

(2) *Extent of continuation.* FFP is available only through the earlier of the following:

(i) The date of issuance of an administrative hearing decision that upholds the agency's termination or nonrenewal action.

(ii) The 120th day after the effective date of termination of the facility's provider agreement or, if the agreement is not terminated, the 120th day after the effective date of expiration. (If a hearing decision that upholds the facility is issued after the end of the 120-day period, when FFP has already been discontinued, the rules of § 442.42 on retroactive agreements apply).

(e) *Applicability of § 441.11.* If FFP is continued during appeal under paragraph (d) of this section, the 30-day period provided by § 441.11 of this chapter would not begin to run until issuance of a hearing decision that upholds the agency's termination or nonrenewal action.

[52 FR 32551, Aug. 28, 1987]

§ 442.42 FFP under a retroactive provider agreement following appeal.

(a) *Basic rule.* Except as specified in paragraph (b) of this section, if a SNF or ICF is upheld on appeal from termination or nonrenewal of a provider agreement, and the State issues a retroactive agreement, FFP is available beginning with the retroactive effective date, which must be determined in accordance with § 442.13.

(b) *Exception.* This rule does not apply if HCFA determines, under § 442.30, that the agreement is not valid evidence that the facility meets the requirements for participation. This exclusion applies even if the State issues the new agreement as the result of an administrative hearing decision favorable to the facility or under a Federal or State court order.

[52 FR 32551, Aug. 28, 1987]

Subpart C—Certification of SNFs, ICFs, and ICFs/MR

§ 442.100 State plan requirements.

A State plan must provide that the requirements of this subpart and Part 483 are met.

[53 FR 20495, June 3, 1988]

EFFECTIVE DATE NOTE: At 53 FR 20495, June 3, 1988, § 442.100 was revised, effective October 3, 1988. For the convenience of the user, the superseded text is set forth below:

§ 442.100 **State plan requirements.**

A State plan must provide that the requirements of this subpart are met.

§ 442.101 Obtaining certification.

(a) This section states the requirements for obtaining notice of a facility's certification before a Medicaid agency executes a provider agreement under § 442.12.

(b) The agency must obtain notice of certification from the Secretary for—

(1) A facility located on an Indian reservation; and

(2) A SNF that has been certified for Medicare payments.

(c) The agency must obtain notice of certification from the survey agency for all other facilities.

(d) The notice must indicate that one of the following provisions pertains to the facility:

(1) The facility meets the applicable requirements:

(i) An SNF meets the requirements in Subpart D of this part and each of the conditions of participation in Part 405, Subpart K of this chapter.

(ii) An ICF meets the requirements in Subparts E and F of this part.

(iii) An ICF/MR meets the requirements of Subpart E of this part and each of the conditions of participation in Part 483, Subpart D of this chapter.

(2) The facility is considered to meet applicable requirements based on waivers or variances granted by HCFA or the survey agency if such waivers or variances are allowed under the applicable subpart.

(3) The facility has been certified with deficiencies in accordance with the following:

(i) An ICF has been certified if deficiencies are covered by an acceptable plan of correction.

(ii) An SNF or ICF/MR has been certified with standard-level deficiencies if—

(A) All conditions of participation are found met; and

(B) The facility submits an acceptable plan of correction covering the remaining deficiencies, subject to other limitations specified in § 442.105.

(e) For SNFs and ICFs/MR, the failure to meet one or more of the applicable conditions of participation is cause for termination or non-renewal of the provider agreement.

[43 FR 45233, Sept. 29, 1978, as amended at 53 FR 20495, June 3, 1988]

Effective Date Note: At 53 FR 20495, June 3, 1988, § 442.101 (d) and (e) was revised, effective October 3, 1988. For the convenience of the user, the superseded text is set forth below:

§ 442.101 Obtaining certification.

* * * * *

(d) The notice must state that the facility—

(1) Meets the applicable requirements under Subpart D, E, F, or G of this part, except for waivers or variations granted by the Secretary or the survey agency under those subparts; or

(2) Has been certified with provision for correcting deficiencies in meeting those requirements, under the conditions of this subpart.

(e) For purposes of certification of facilities under this subpart, a waiver of standards is not a deficiency.

§ 442.105 Certification with standard-level deficiencies: General provisions.

If a survey agency finds a facility deficient in meeting the standards specified under Subpart D, E or F of this part or under Subpart D of Part 483, the agency may certify the facility for Medicaid purposes under the following conditions:

(a) The agency finds that the facility's deficiencies, individually or in combination, do not jeopardize the patient's health and safety, nor seriously limit the facility's capacity to give adequate care. The agency must maintain a written justification of these findings.

(b) The agency finds acceptable the facility's written plan for correcting the deficiencies.

(c) If a facility was previously certified with a deficiency and has a different deficiency at the time of the next survey, the agency documents that the facility—

(1) Was unable to stay in compliance with the standard for reasons beyond its control, or despite intensive efforts to comply; and

(2) Is making the best use of its resources to furnish adequate care.

(d) If a facility has the same deficiency it had under the prior certification, the agency documents that the facility—

(1) Did achieve compliance with the standard at some time during the prior certification period;

(2) Made a good faith effort, as judged by the survey agency, to stay in compliance; and

(3) Again became out of compliance for reasons beyond its control.

(e) If an ICF or ICF/MR has a deficiency of the types specified in § 442.111 or § 442.112 that requires a plan of correction extending beyond 12 months, the agency documents that the conditions of those sections are met.

[43 FR 45233, Sept. 29, 1978, as amended at 53 FR 20496, June 3, 1988]

Effective Date Note: At 53 FR 20496, June 3, 1988, § 442.105, was amended by revising the title and the introductory paragraph, effective October 3, 1988. For the convenience of the user, the superseded text is set forth below:

§ 442.105 Certification with deficiencies: General provisions.

If survey agency finds a facility deficient in meeting the standards specified under Subpart D, E, F, or G of this part, the agency may certify the facility for Medicaid purposes under the following conditions:

* * * * *

§ 442.109 Certification period: General provisions.

(a) A survey agency may certify a facility that fully meets applicable requirements for up to 12 months.

(b) The survey agency may notify the Medicaid agency that the term of a provider agreement may be extended up to 2 months after the expiration date of the agreement under the conditions specified in § 442.16.

[43 FR 45233, Sept. 29, 1978. Redesignated at 53 FR 1993, Jan. 25, 1988]

§ 442.110 Certification period: Facilities with standard-level deficiencies.

(a) Facilities with deficiencies may be certified under § 442.105 for the period specified in either paragraph (b) or (c) of this section. However, ICF's with deficiencies that may require more than 12 months to correct may be certified under §§ 442.111 and 442.112.

(b) The survey agency may certify a facility for a period that ends no later than 60 days after the last day specified in the plan for correcting deficiencies. The certification period must not exceed 12 months, including the period allowed for corrections.

(c) The survey agency may certify a facility for up to 12 months with a condition that the certification will be automatically canceled on a specified date within the certification period unless—

(1) The survey agency finds that all deficiencies have been satisfactorily corrected; or

(2) The survey agency finds and notifies the Medicaid agency that the facility has made substantial progress in correcting the deficiencies and has a new plan for correction that is acceptable.

The automatic cancellation date must be no later than 60 days after the last day specified in the plan for correction of deficiencies under § 442.105.

[43 FR 45233, Sept. 29, 1978. Redesignated and amended at 53 FR 1993, Jan. 25, 1988; 53 FR 20496, June 3, 1988]

Effective Date Note: At 53 FR 20496, June 3, 1988, in § 442.110, the heading was revised, by inserting the words "standard-level" between "with" and "deficiencies", effective October 3, 1988.

§ 442.111 Extended period for correcting deficiencies: ICFs other than ICFs/MR; environment, sanitation and Life Safety Code deficiencies.

(a) *Scope.* This section applies to ICF's other than ICF's/MR that are deficient in meeting requirements for—

(1) Environment and sanitation (§§ 442.324 through 442.330); or

(2) Life Safety Code (§§ 442.321 through 442.323).

(b) *Certification period.* The survey agency may certify an ICF other than an ICF/MR under § 442.105 for up to 12 months even though the facility has deficiencies that may take up to 2 years after the first certification of the facility to correct, if the conditions in this section are met.

(c) *Written plan for correction.* The ICF must submit a written plan for correcting the deficiencies that—

(1) Specifies the steps the facility will take to correct each deficiency;

(2) Specifies a timetable for taking each of those steps and a date for completion of correction of each deficiency that is not later than 2 years after the date the facility is first certified; and

(3) Is acceptable to the survey agency.

(d) *Feasibility of plan.* The survey agency must find that the facility can—

(1) Potentially meet the requirements in which it is deficient by taking the steps specified in the plan for correction; and

(2) Correct each deficiency by the date specified in the plan for correction.

(e) *Progress in meeting correction plan.* Within each 6-month period after acceptance of the plan for correction, the survey agency must find, and record in the survey record, that the facility has made substantial progress in meeting its plan for correction. These findings must be based on onsite surveys by qualified surveyors. The survey agency must support these findings by placing signed contracts, work orders, or other documents in the survey record.

(f) *State fire safety and sanitation requirements.* The survey agency must find that, during the period allowed for corrections, the facility meets State fire safety and sanitation codes and regulations.

[43 FR 45233, Sept. 29, 1978. Redesignated and amended at 53 FR 1993, Jan. 25, 1988]

§ 442.112 Extended period for correcting deficiencies: ICFs/MR; Life Safety Code and living/dining/therapy area deficiencies.

(a) *Scope.* This section applies to ICF's/MR that are deficient in meeting requirements for—

(1) Life Safety Code (§§ 442.507-442.509);

(2) Living units (§§ 442.447(a) (1), (2), (4), (5), (b), (c), 442.448(d), 442.449 (a), (b), 442.450(a)(2), 442.451(a), 442.452, 442.453);

(3) Dining rooms (§ 442.471(a)-(c)); or

(4) Therapy areas (§ 442.488(e)).

(b) *Certification period.* The survey agency may certify an ICF/MR under § 442.105 for up to 12 months even though the deficiencies listed in paragraph (a) of this section may take more than 12 months to correct, if the conditions in this section and § 442.115 are met.

(c) *Written plan for correction.* Before certifying an ICF/MR under this section, the survey agency must approve, in writing, the ICF/MR's written plan for correcting those deficiencies. The plan must—

(1) State the extent to which the ICF/MR complies with the requirements it does not fully meet;

(2) Specify the steps the ICF/MR will take to correct the deficiencies;

(3) Specify a timetable for taking each of those steps and a date for completion of corrections;

(4) For a public ICF/MR, be approved by the State or political subdivision that has jurisdiction over its operation (A public facility is defined in § 435.1009 of this subchapter as one that is the "responsibility of a governmental unit or over which a governmental unit exercises administrative control."); and

(5) Meet the conditions of § 442.113.

(d) *Progress in meeting correction plan.* Within each 6-month period after initial approval of the plan, the survey agency must find, and record in the survey record, that the ICF/MR has made substantial progress in meeting the plan for correction. These findings must be based on onsite surveys by qualified surveyors. The survey agency must support these findings by placing signed contracts, work orders, or other documentation in the survey record.

(e) *State fire safety and sanitation requirements.* The survey agency must find that, during the period allowed for corrections, the ICF/MR meets the State fire safety and sanitation codes and regulations.

[43 FR 45233, Sept. 29, 1978. Redesignated and amended at 53 FR 1993 and 1994, Jan. 25, 1988]

§ 442.113 Correction plans for ICFs/MR: Life Safety Code and living/dining/therapy area deficiencies.

(a) The ICF/MR's plan required by § 442.112 must provide for completion of corrections by:

(1) July 18, 1980; or

(2) July 18, 1982, if authorized by HCFA under paragraph (b) or (e) of this section; or

(3) the date approved by HCFA, if authorized by HCFA under paragraph (f) of this section; or

(4) the date approved by HCFA, if authorized by HCFA under paragraph (g) of this section, when corrections of deficiencies in units to be retained are completed within the appropriate time period as set forth in paragraph (g) of this section.

(b) If, at the time of the first survey of the ICF/MR after July 17, 1977, it is unable to develop a plan to complete corrections by July 18, 1980, the survey agency may request HCFA to authorize approval of a plan to complete them by July 18, 1982. HCFA will authorize this approval for each deficiency if it is determined that time beyond July 18, 1977, is needed—

(1) As a practical matter to complete the corrections;

(2) To prevent unreasonable hardship to the ICF/MR; and

(3) To insure continued care for recipients served by the ICF/MR.

(c) If the plan provides for correction through structural change or renovation, it must—

(1) Contain a timetable showing the corrective steps and their completion dates;

(2) Specify the structural change or renovation; and

(3) Document that sufficient financial resources are available to complete the change or renovation on schedule.

(d) If the plan provides for correction by phasing out part or all of the ICF/MR, it must—

(1) Contain a timetable showing the buildings or units to be closed and describing the steps for phasing them out;

(2) Describe the methods that insure the recipients' health and safety until the building or unit is closed; and

(3) Provide that no new recipients will be admitted to the building or unit after the plan has been approved.

(e) If an ICF/MR is unable to complete corrections required by the plan of correction by July 18, 1980 and it did not request an extension beyond that date under paragraph (b) of this section, the survey agency may request HCFA to authorize approval for an extension of the facility's plan of correction to July 18, 1982 if—

(1) For corrections under paragraph (c) of this section, the facility provides documentation from the renovation project's supervising architect or contractor that required construction work was at least 25 percent completed by July 18, 1980 and will be completed by July 18, 1982;

(2) For corrections under paragraph (d) of this section, the facility provides documentation that the phase out program was at least 25 percent completed on July 18, 1980 and will be completed by July 18, 1982; and

(3) The survey agency finds that all continuing deficiencies covered by the plan of correction will be resolved by completion of the construction, renovation, or phase out of beds.

(f) If an ICF/MR is unable to complete corrections required by the plan of correction by July 18, 1980 or July 18, 1982, as authorized in paragraphs (a), (b) and (e) of this section, the survey agency may request HCFA to authorize a plan of correction for an additional period of time if the delay was caused by litigation, provided that—

(1) The United States, or any agency or Department thereof, was party to the litigation, or was an intervenor in it, or participated as an *amicus curiae;* and

(2) The United States advocated a position which caused or contributed, in whole or in part, to the delay; and

(3) The request for an additional period of time to complete corrections under this provision does not exceed the amount of the delay resulting from the litigation, as determined by HCFA.

(g) The survey agency may request HCFA by November 24, 1982 to approve a revision to the existing correction plan of an ICF/MR under this section if the facility chooses to engage in a partial or complete phase out of beds in certified units of the facility already contained in the present correction plan as follows:

(1) The extended phase out period to be approved by HCFA may be 1 to 5 years from August 26, 1982 if the facility:

(i) Provides documentation that it has completed at least 25 percent of the items in the original correction plans under paragraphs (c) and (d) of this section;

(ii) Increases the total number of beds being phased out within certified units;

(iii) Agrees to a rate of decline in resident population, and establishes, in the revised correction plan submitted under this paragraph, targets at six-month intervals for the phasing out of a specific number of beds;

(iv) Assures the health and safety of the residents until the buildings or units are phased out; and

(v) Ensures that only residents who are classified for the ICF/MR level of care when the revised correction plan submitted under this paragraph is approved, will be admitted thereafter to the buildings or units being phased out.

(2) The survey agency must ensure that the facility has met all the facility standards for ICFs/MR (Subpart G of this part), or has an approved plan of correction for those certified buildings and units in use and to be retained after the phase out plan is completed; and

(3) The facility may not seek certification of units not currently certified in order to add the beds in those units to an expanded phase out plan as a means of taking advantage of this regulation.

(4) FFP will not be available for costs attributable to any beds which remain above the targeted phase out goals after each 6-month target date is passed.

(Secs. 1102, 1905(c) and 1905(d) of the Social Security Act (42 U.S.C. 1302, 1396d(c), 1396(d))

[47 FR 37549, Aug. 26, 1982. Redesignated and amended at 53 FR 1993 and 1994, Jan. 25, 1988]

§ 442.114 Correction and reduction plans for ICFs/MR: General provisions.

(a) *Options of Medicaid agency.* If HCFA finds substantial deficiencies only in physical plant and staffing that do not pose an immediate threat to the clients' health and safety in an ICF/MR, HCFA will forward the list of deficiencies to the Medicaid agency and the agency may elect to—

(1) Submit to HCFA within 30 days of receipt of the list of deficiencies a written plan of correction in accordance with § 442.115, as permitted by § 442.105; or

(2) Submit to HCFA within 65 days of receipt of the list of deficiencies a written plan to reduce permanently the number of beds in certified units in accordance with § 442.116. The purpose of the reduction plan is to vacate any noncomplying buildings (or distinct parts thereof) and correct any staff deficiencies within 36 months of the approval of the plan.

(b) *Option limitation for Medicaid agency.* An ICF/MR found to have substantial deficiencies in physical plant and staffing, and substantial deficiencies in other areas of care is not eligible for either a correction or reduction plan under this section.

(c) *HCFA options.* (1) If the Medicaid agency does not comply with paragraph (a) of this section, HCFA may cancel approval of the deficient ICF/MR's participation in the Medicaid program in accordance with section 1910(c) of the Act.

(2) HCFA will respond in writing to the agency within 30 days from receipt of a proposed correction plan submitted under paragraph (a)(1) of this section.

(d) *Duration.* The provisions of this section and §§ 442.115 and 442.116 apply only to correction and reduction plans approved by HCFA within 3 years after Federal surveys initiated in ICF/MRs on or after April 7, 1986.

[53 FR 1994, Jan. 25, 1988]

§ 442.115 Correction plans for ICFs/MR: Specific requirements.

(a) *Contents.* A correction plan under § 442.114(a)(1) must include—

(1) An explanation of the extent to which the ICF/MR currently complies with the standards for ICFs/MR in Subpart G including all deficiencies identified during a direct Federal survey, and

(2) A timetable for completing the necessary steps to correct staff and physical plant deficiencies on which the request for a correction plan is based, and all other minor deficiencies, within 6 months of the approval date of the plan.

(b) *HCFA policies.* HCFA considers a correction plan only if HCFA received it within 30 days of receipt by the Medicaid agency of the list of deficiencies referred to in § 442.114(a). After consideration of the plan, HCFA will forward in writing its approval or disapproval within 30 days of receipt of the proposed correction plan.

(c) *Exception.* If, as a result of a public hearing, the Medicaid agency decides that a reduction plan is not appropriate, and instead decides to submit a correction plan, the correction plan must be received by HCFA within 20 days from the date of the public hearing.

(d) *Termination of an ICF/MR.* (1) If the Medicaid agency submits a correction plan that HCFA finds to be unacceptable, HCFA will notify the agency of its disapproval and will terminate the ICF/MR's participation in the Medicaid program in accordance with section 1910(c) of the Act.

(2) If, at the conclusion of the 6-month period specified in the plan of correction described in paragraph (a) of this section, HCFA determines that the agency has substantially failed to correct the deficiencies identified, HCFA may terminate the ICF/MR from participating in the Medicaid program in accordance with section 1910(c) of the Act.

[53 FR 1994, Jan. 25, 1988]

§ 442.116 Reduction plans for ICFs/MR: Specific requirements.

(a) *Conditions of approval: Agency requirements.* Before submitting a reduction plan under § 442.114(a)(2) to HCFA, the Medicaid agency must—

(1) Conduct a public hearing at the affected ICF/MR at least 35 days before submitting the reduction plan to HCFA that outlines the—

(i) Contents of the reduction plan,

(ii) Process for submitting the plan to HCFA, and

(iii) Process for submitting public comments to HCFA within 30 days of receipt of the reduction plan by HCFA.

(2) Provide written notice of the hearing to staff, clients and their parents or guardians, and the nearest, most interested, or involved family member or party, as appropriate, at least 10 days prior to the hearing date.

(3) Announce to advocacy and other interested groups and agencies; the courts with which the ICF/MR is involved in litigation (if any) arising out of its Medicaid participation; and the general community; through local media notices, at least 10 days prior to the hearing date—

(i) The exact date, time and location of the hearing; and

(ii) The locations (that is, the affected ICF/MR, the State mental retardation administration, State survey agency, State Developmental Disabilities Council, State and local protection and advocacy agencies and other agencies, which in the State's judgment, serve potentially interested parties (for example, State and local associations for retarded citizens)) where the proposed plan is displayed.

(4) Demonstrate that it has successfully provided home and community services similar to those services proposed to be provided under the reduction plan for similar individuals eligible for Medicaid by including—

(i) Documentation of existing programs and level of funding, and

(ii) Projections for growth and how the growth will be funded to accommodate the clients being displaced by the reduction plan.

(5) Provide assurances to HCFA that the reduction plan will be completed by fulfilling the content requirements of the reduction plan contained in paragraph (d) of this section.

(b) *Withdrawal by a Medicaid agency of a proposed reduction plan.* If, after the public hearing, a Medicaid agency decides a reduction plan would not be appropriate, the agency may choose to proceed with a plan of correction in accordance with the requirements contained in §§ 442.115 (a) and (c).

(c) *Submittal date of plan.* On the day that the Medicaid agency submits a reduction plan, the agency must announce through local media notices—

(1) That the plan has been submitted to HCFA;

(2) That the plan is on display at the affected ICF/MR, the State mental retardation administration, State survey agency, State Developmental Disabilities Council, State and local protection and advocacy agencies, and other agencies, which in the State's judgment, serve potentially interested parties (for example, State and local associations for retarded citizens); and

(3) The address of the appropriate HCFA office for forwarding comments on the reduction plan and the closing date for receipt of those comments.

(d) *Contents.* A reduction plan must—

(1) Identify the number of clients and their service needs on a client-by-client basis for home or community services, and a timetable for providing such services, in 6-month intervals, within the 36-month period beginning

on the date that the reduction plan is approved by HCFA;

(2) Describe the methods used to—

(i) Select clients for home or community services, and

(ii) Develop alternative home and community services to effectively meet the clients' needs;

(3) Describe the safeguards that will be applied to protect the clients' health and welfare while receiving home or community services, including—

(i) Adequate standards for participation by clients, clients' families and providers; and

(ii) Assurances that the community residences in which the affected clients are placed meet all applicable State and Federal licensure and certification requirements;

(4) Provide that clients who are eligible for medical assistance while in the ICF/MR will, at their option, be placed in another setting (or another part of the ICF/MR) so as to retain their eligibility for medical assistance.

(5) Specify the actions to protect the health and safety of the clients remaining in the ICF/MR while the reduction plan is in effect;

(6) Provide that the staff-to-client ratio at the ICF/MR will be the higher of—

(i) The ratio described in the standards for ICFs and ICFs/MR (§ 442.445); or

(ii) The ratio which was in effect at the time the direct Federal survey was conducted; and

(7) Provide for the protection of the staff affected by the reduction plan, including—

(i) Arrangements to preserve staff rights and benefits;

(ii) Training and retraining of staff where necessary;

(iii) Redeploying staff to community settings under the reduction plan; and

(iv) Making maximum efforts to secure employment (without necessarily guaranteeing the employment of any staff).

(e) *HCFA policies.* (1) HCFA will consider approval of reduction plans on a first come, first served basis. HCFA will provide the public at least 30 days after the Medicaid agency submits a reduction plan to comment on the proposed plan. After the close of the public comment period, HCFA will forward in writing its approval or disapproval of the reduction plan to the agency within 30 days.

(2) If HCFA approves more than 15 reduction plans in any fiscal year, any reduction plans approved in addition to the first 15 approved plans, will be for an ICF/MR (or distinct part thereof) for which the costs of correcting the substantial deficiencies are $2 million or greater (as demonstrated by the Medicaid agency to the satisfaction of HCFA).

(3) HCFA may approve reduction plans for a shorter period than 36 months, where applicable.

(4) HCFA approval of a reduction plan does not constitute approval of any request for a home and community-based waiver. Home and community-based waivers are subject to HCFA review and approval under § 441.300 of this chapter. Disapproval of a request for a home and community-based waiver constitutes disapproval of a request for a reduction plan that is dependent upon approval of the request for a home and community-based waiver.

(f) *Termination of an ICF/MR.* (1) If the Medicaid agency submits a reduction plan that HCFA finds to be unacceptable, HCFA will notify the agency of its disapproval and terminate the ICF/MR's participation in the Medicaid program in accordance with section 1910(c) of the Act.

(2) If, at the conclusion of the initial 6-month period or any 6-month interval thereafter of the reduction plan, HCFA determines that the Medicaid agency has substantially failed to meet the requirements of paragraph (a) of this section, HCFA will—

(i) Terminate the ICF/MR from participating in the Medicaid program in accordance with section 1910(c) of the Act, or

(ii) Disallow FFP equal to 5 percent of the cost of care for all eligible clients for each month for which the agency failed to meet the requirements despite good faith efforts it may have made.

[53 FR 1994, Jan. 25, 1988]

§ 442.117 Termination of certification for facilities whose deficiencies pose immediate jeopardy.

(a) A survey agency must terminate a facility's certification if it determines that—

(1) The facility no longer meets applicable conditions of participation (for SNFs and ICFs/MR) or standards (for ICFs) specified under Subpart D, E, and F of this part or Part 483, Subpart D of this chapter; and

(2) The facility's deficiencies pose immediate jeopardy to patients' health and safety.

(b) Subsequent to a certification of a facility's noncompliance, the Medicaid agency must, in terminating the provider agreement, follow the appeals process specified in Part 431, Subpart D of this chapter.

[51 FR 24491, July 3, 1986, as amended at 53 FR 20496, June 3, 1988]

EFFECTIVE DATE NOTE: At 53 FR 20496, June 3, 1988, in § 442.117, paragraph (a) (1) was revised, effective October 3, 1988. For the convenience of the user, the superseded text is set forth below:

§ 442.117 Termination of certification for facilities whose deficiencies pose immediate jeopardy.

(a) * * *

(1) The facility no longer meets applicable conditions of participation (for SNFs) or standards (for ICFs and ICFs/MR) specified under Subpart D, E, F, or G of this part, and

* * * * *

§ 442.118 Denial of payments for new admissions.

(a) *Basis for denial of payments.* The Medicaid agency may deny payment for new admissions to a SNF, ICF, or ICF/MR that no longer meets the applicable conditions of participation (for SNFs) or standards (for ICFs and ICFs/MR) specified under Subpart D, E, F, or G of this part if either of the following conditions is met:

(1) *Facility's deficiencies do not pose immediate jeopardy.* If the agency finds that the facility's deficiencies do not pose immediate jeopardy to patients health and safety, the agency may either terminate the facility's provider agreement or deny payment for new admissions.

(2) *Facility's deficiencies do pose immediate jeopardy.* If the agency finds that the facility's deficiencies do pose immediate jeopardy to patients' health and safety and thereby terminates the facility's provider agreement, the agency may additionally seek to impose the denial of payment sanction.

(b) *Agency procedures.* Before denying payments for new admissions, the Medicaid agency must comply with the following requirements:

(1) Provide the facility up to 60 days to correct the cited deficiencies and comply with the conditions (for SNFs and ICFs/MR) or the standards (for ICFs).

(2) If at the end of the specified period the facility has not achieved compliance, give the facility notice of intent to deny payment for new admissions, and opportunity for an informal hearing.

(3) If the facility requests a hearing, provide an informal hearing that includes—

(i) The opportunity for the facility to present, before a State Medicaid official who was not involved in making the initial determination, evidence or documentation, in writing or in person, to refute the decision that the facility is out of compliance with the applicable conditions of participation (for SNFs and ICFs/MR) or standards (for ICFs) participation; and

(ii) A written decision setting forth the factual and legal bases pertinent to a resolution of the dispute.

(4) If the decision of the informal hearing is to deny payments for new admissions, provide the facility and the public, at least 15 days before the effective date of the sanction, with a notice that includes the effective date and the reasons for the denial of payments.

(c) *Effect of denial of Medicare payment*—(1) *Period of denial.* If HCFA denies Medicare payments for new admissions to a SNF that also participates in Medicaid, the Medicaid agency must deny Medicaid payments for new admissions, effective for the same time period that Medicare payments are denied.

(2) *Informal hearing.* Only one informal hearing is available to a SNF that participates in both programs. It would be provided by HCFA in accordance with § 489.62(c) of this chapter.

[51 FR 24491, July 3, 1986, as amended at 53 FR 20496, June 3, 1988]

Effective Date Note: At 53 FR 20496, June 3, 1988, § 442.118 (b)(1) and (b)(3)(i) was amended, effective October 3, 1988. Paragraph (b)(1) was amended by adding the phrase "ICFs/MR" after "SNFs", and paragraph (b)(3)(i) was amended by removing the phrase "conditions of participation (for SNFs) or standards (for ICFs and ICFs/MR)" and adding in its place the phrase "conditions of participation (for SNFs and ICFs/MR or standards (for ICFs)."

§ 442.119 Duration of denial of payments and subsequent termination.

(a) *Period of denial.* The denial of payments for new admissions will continue for 11 months after the month it was imposed unless, before the end of that period, the Medicaid agency finds that—

(1) The facility has corrected the deficiencies or is making a good faith effort to achieve compliance with the conditions of participation (for SNFs and ICFs/MR) or standards (for ICFs); or

(2) The deficiencies are such that it is necessary to terminate the facility's provider agreement.

(b) *Subsequent termination.* The Medicaid agency must terminate a facility's provider agreement—

(1) Upon the agency's finding that the facility has been unable to achieve compliance with the conditions of participation (for SNFs and ICFs/MR) or standards (for ICFs) during the period that payments for new admissions have been denied;

(2) Effective the day following the last day of the denial of payments period; and

(3) In accordance with the procedures for appeal of terminations set forth in Subpart D of Part 431 of this chapter.

[51 FR 24491, July 3, 1986, as amended at 53 FR 20496, June 3, 1988]

Effective Date Note: At 53 FR 20496, June 3, 1988, § 442.119(a)(1) and (b)(1) were amended by removing the phrase "conditions of participation (for SNFs) or standards (for ICFs and ICFs/MR)" and adding in its place the phrase "conditions of participation (for SNFs and ICFs/MR) or standards (for ICFs)", effective October 3, 1988.

Subpart D—Skilled Nursing Facility Requirements

§ 442.200 Purpose.

This subpart specifies the requirements that a SNF must meet to obtain certification from the Secretary or the State survey agency as a qualified Medicaid provider of SNF services.

§ 442.201 State licensing standards.

(a) A SNF must meet State nursing home licensing standards. However, if a SNF that formerly met State licensing standards does not currently meet them, it may continue to receive Medicaid payments as a qualified provider during a period specified by the responsible licensing authority if, during that period, the SNF takes the steps needed to again meet the standards.

(b) For purposes of this subpart, the fact that a SNF actually holds a current license is immaterial if the responsible State licensing authority determines that, in fact, the standards are not met.

(c) In accordance with § 431.110 of this subchapter, an Indian Health Service SNF must meet State licensing standards although it need not obtain a license. In making this determination, the licensing authority may not take into account an absence of licensure of any staff member of the facility.

§ 442.202 Federal definitions and standards.

The SNF must meet—

(a) The definition of a "skilled nursing facility" in § 440.40(a) of this subchapter;

(b) The definition in section 1861(j) of the Act; and

(c) The standards specified in Part 405, Subpart K, of this chapter: Conditions of participation; skilled nursing facilities, except for provisions waived under that subpart or accepted by the Secretary or the State survey agency under a plan of correction as specified in Subpart B of this part. Provisions that may be waived under Part 405, Subpart K, include:

(1) Building accessibility, § 405.1134(c);

(2) Patient room and toilet facilities, § 405.1134(e); and

(3) Utilization review, § 405.1137, if authorized under §§ 456.501-456.508 of this subchapter.

Subpart E—Intermediate Care Facility Requirements; All Facilities

§ 442.250 Purpose.

This subpart specifies the requirements that an ICF must meet to obtain certification from the State survey agency as a qualified provider of ICF services.

§ 442.251 State licensing standards.

(a) Except as provided in paragraph (b) of this section, an ICF must meet standards for a State license to provide, on a regular basis, health-related care and services to individuals who do not require hospital or SNF care, but whose mental or physical condition requires services—

(1) Above the level of room and board; and

(2) That can be provided only by an institution.

(b) An ICF that formerly met State licensing standards but does not currently meet them may continue to receive Medicaid payments as a qualified provider during a period specified by the State authority responsible for licensing the facility if, during that period, the ICF takes the steps needed to again meet the standards.

(c) An ICF operated by a government agency must meet the licensing standards that apply to the same type of facility operated under any other ownership.

(d) In accordance with § 431.110 of this subchapter, an Indian Health Service ICF must meet State licensing standards although it need not obtain a license. In making this determination, the licensing authority may not take into account an absence of licensure of any staff member of the facility.

§ 442.252 State safety and sanitation standards.

An ICF must meet State safety and sanitation standards for nursing homes.

Effective Date Note: At 53 FR 20496, June 3, 1988, § 442.252 was removed, effective Oct. 3, 1988.

§ 442.253 Federal definition and standards.

(a) An ICF other than an ICF/MR must meet the definition in § 440.150 of this subchapter and the standards specified in this subpart and Subpart F of this part, except for provisions waived or accepted under plans of corrections as specified in Subpart C of this part.

(b) An ICF/MR must meet the definition in § 440.150 of this subchapter and the standards specified in this subpart and Subpart G of this part, except for provisions waived or accepted under plans of correction as specified in Subpart C of this part.

§ 442.254 Standards for hospitals and SNF's providing ICF services.

(a) If a hospital or SNF participating in Medicare or Medicaid is also a provider of ICF services other than ICF/MR services, it must meet the following ICF standards:

(1) Section 442.304, resident services director.

(2) Section 442.317 (a), (b), agreements with outside resources for institutional services.

(3) Section 442.319, plan of care.

(4) Section 442.320, resident financial records.

(5) Section 442.324 (b), handrails.

(6) Section 442.338 through 442.342, health services.

(7) Section 442.343, rehabilitative services.

(8) Section 442.344, social services.

(9) Section 442.345, activities program.

(10) Section 442.346, physician services.

(b) If a hospital or SNF participating in Medicare or Medicaid is also a provider of ICF/MR services, it must meet each of the conditions of participation specified in Part 483, Subpart D of this chapter.

[43 FR 45233, Sept. 29, 1978, as amended at 53 FR 20496, June 3, 1988]

EFFECTIVE DATE NOTE: At 53 FR 20496, June 3 1988, § 442.254 (b) was revised, effective October 3, 1988. For the convenience of the user, the superseded text is set forth below:

§ 442.254 Standards for hospitals and SNF's providing ICF services.

* * * * *

(b) If a hospital or SNF participating in Medicare or Medicaid is also a provider of ICF/MR services, it must meet the standards in Subpart G of this part.

Subpart F—Standards for Intermediate Care Facilities Other Than Facilities for the Mentally Retarded

§ 442.300 Basis, purpose, and scope.

This subpart implements section 1905(c) of the Act, which gives the Secretary authority to prescribe standards for care, safety, and sanitation in intermediate care facilities. It applies to ICF's other than ICF's/MR.

ADMINISTRATION

§ 442.301 Methods of administration.

An ICF must have methods of administrative management that insure that it meets the requirements of §§ 442.302 through 442.315.

§ 442.302 Staffing.

The ICF must have staff on duty 24 hours a day sufficient in number and qualifications to carry out the policies, responsibilities, and programs of the ICF.

§ 442.303 Administrator.

(a) The ICF must have an administrator who is—

(1) A nursing home administrator with a current State license; or

(2) A hospital administrator, if the ICF is a hospital qualifying as an intermediate care facility.

(b) The administrator's responsibilities must include—

(1) Managing the ICF; and

(2) Implementing established policies and procedures.

§ 442.304 Resident services director.

(a) The ICF must designate the administrator or a professional staff member as resident services director.

(b) The duties of the resident services director must include coordinating and monitoring each resident's overall plan of care.

§ 442.305 Written policies and procedures: General requirements.

The ICF must have written policies and procedures that—

(a) Govern all services provided by the ICF; and

(b) Are available to the staff, residents, members of the family and legal representatives of residents, and the public.

§ 442.306 Written policies and procedures: Admission.

The ICF must have written policies and procedures that insure that it admits as residents only those individuals whose needs can be met—

(a) By the ICF itself;

(b) By the ICF in cooperation with community resources; or

(c) By the ICF in cooperation with other providers of care affiliated with or under contract to the ICF.

§ 442.307 Written policies and procedures: Transfer and discharge.

The ICF must have written policies and procedures that insure that—

(a) It transfers a resident promptly to a hospital, skilled nursing facility, or other appropriate facility, when a change occurs in the resident's physical or mental condition that requires care or service that the ICF cannot adequately provide; and

(b) Except in an emergency, it—

(1) Consults the resident, his next of kin, the attending physician, and the responsible agency, if any, at least 5 days before a transfer or discharge; and

(2) Uses casework services or other means to insure that adequate arrangements are made to meet the resident's needs through other resources.

§ 442.308 Written policies and procedures: Chemical and physical restraints.

The ICF must have written policies and procedures that—

(a) Define the uses of chemical and physical restraints;

(b) Identify the professional personnel who may, under § 442.311(h), authorize use of these restraints in emergencies; and

(c) Describe the procedures for monitoring and controlling the use of these restraints.

§ 442.309 Written policies and procedures: Resident complaints and recommendations.

The ICF must have written policies and procedures that—

(a) Describe the procedures the ICF uses to receive complaints and recommendations from its residents; and

(b) Insure that the ICF responds to these complaints and recommendations.

§ 442.310 Written policies and procedures: Resident records.

The ICF must have written policies and procedures governing access to, duplication of, and dissemination of information from the resident's record.

§ 442.311 Written policies and procedures: Residents' bill of rights.

The ICF must have written policies and procedures that insure the following rights for each resident:

(a) *Information.* (1) Each resident must be fully informed, before or at the time of admission, of his rights and and responsibilities and of all rules governing resident conduct.

(2) If the ICF amends its policies on residents' rights and responsibilities and its rules governing conduct, each resident in the ICF at that time must be informed.

(3) Each resident must acknowledge in writing receipt of the information and any amendments to it.

(4) Each resident must be fully informed in writing of all services available in the ICF and of the charges for these services including any charges for services not paid for by Medicaid or not included in the ICF's basic rate per day. The ICF must provide this information either before or at the time of admission and on a continuing basis as changes occur in services or charges during the resident's stay.

(b) *Medical condition and treatment.* (1) Each resident must—

(i) Be fully informed by a physician of his health and medical condition unless the physician decides that informing the resident is medically contraindicated;

(ii) Be given the opportunity to participate in planning his total care and medical treatment;

(iii) Be given the opportunity to refuse treatment; and

(iv) Give informed, written consent before participating in experimental research.

(2) If the physician decides that informing the resident of his health and medical condition is medically contraindicated, the physician must document this decision in the resident's record.

(c) *Transfer and discharge.* Each resident must be transferred or discharged only for—

(1) Medical reasons;

(2) His welfare or that of the other residents; or

(3) Nonpayment except as prohibited by the Medicaid program.

(d) *Exercising rights.* Each resident must be—

(1) Encouraged and assisted to exercise his rights as a resident of the ICF and as a citizen; and

(2) Allowed to submit complaints or recommendations concerning the policies and services of the ICF to staff or to outside representatives of the resident's choice or both, free from restraint, interference, coercion, discrimination, or reprisal.

(e) *Financial affairs.* The ICF must comply with the requirements specified in § 405.1121(m) of this chapter with respect to the protection of patients' personal funds.

(f) *Freedom from abuse and restraints.* (1) Each resident must be free from mental and physical abuse.

(2) Each resident must be free from chemical and physical restraints unless the restraints are—

(i) Authorized by a physician in writing for a specified period of time; or

(ii) Used in an emergency under the following conditions:

(A) The use is necessary to protect the resident from injuring himself or others.

(B) The use is authorized by a professional staff member identified in the written policies and procedures of the facility as having the authority to do so.

(C) The use is reported promptly to the resident's physician by that staff member.

(g) *Privacy.* (1) Each resident must be treated with consideration, respect, and full recognition of his or her dignity and individuality.

(2) Each resident must be given privacy during treatment and care of personal needs.

(3) Each resident's records, including information in an automatic data bank, must be treated confidentially.

(4) Each resident must give written consent before the ICF may release information from his record to someone not otherwise authorized by law to receive it.

(5) A married resident must be given privacy during visits by his spouse.

(6) If both husband and wife are residents of the ICF, they must be permitted to share a room.

(h) *Work.* No resident may be required to perform services for the ICF.

(i) *Freedom of association and correspondence.* Each resident must be allowed to—

(1) Communicate, associate, and meet privately with individuals of his choice, unless this infringes on the rights of another resident; and

(2) Send and receive personal mail unopened.

(j) *Activities.* Each resident must be allowed to participate in social, religious, and community group activities.

(k) *Personal possessions.* Each resident must be allowed to retain and use his personal possessions and clothing as space permits.

§ 442.312 Written policies and procedures: Delegation of rights and responsibilities.

(a) The ICF must have written policies and procedures that provide that all rights and responsibilities of a resident pass to the resident's guardian, next of kin, or sponsoring agency or agencies if the resident—

(1) Is adjudicated incompetent under State law; or

(2) Is determined by his physician to be incapable of understanding his rights and responsibilities.

(b) If the resident is determined to be incapable of understanding his rights and responsibilities, the physician who made the determination must record the specific reason in the resident's record.

§ 442.313 Emergencies.

The ICF must—

(a) Have a written plan for staff and residents to follow in case of an emergency such as a fire or an explosion and rehearse the plan regularly; and

(b) Have written procedures for the staff to follow in case of an emergency involving a resident. These emergency procedures must include directions for—

(1) Caring for the resident;

(2) Notifying the attending physician and other individuals responsible for the resident; and

(3) Arranging for transportation, hospitalization, or other appropriate services.

§ 442.314 Staff training programs.

The ICF must—

(a) Conduct an orientation program for all new employees that includes a review of all its policies;

(b) Plan and conduct an inservice staff development program for all personnel to assist them in developing and improving their skills; and

(c) Maintain a record of each orientation and staff development program it conducts. The record must include the content of the program and the names of the participants.

§ 442.315 Health and safety laws.

The ICF must meet all Federal, State, and local laws, regulations, and codes pertaining to health and safety, such as provisions regulating—

(a) Buying, dispensing, safeguarding, administering, and disposing of medications and controlled substances;

(b) Construction, maintenance, and equipment for the ICF;

(c) Sanitation;

(d) Communicable and reportable diseases; and

(e) Post mortem procedures.

§ 442.316 Transfer agreements.

(a) Except as provided in paragraph (b) of this section, the ICF must have in effect a transfer agreement with one or more hospitals sufficiently close by to make feasible the prompt transfer of the resident and his records to the hospital and to support a working arrangement between the ICF and the hospital for providing inpatient hospital services to residents when needed.

(b) If the survey agency finds that the ICF tried in good faith to enter into an agreement but could not, the ICF will be considered to meet the requirements of paragraph (a) of this section, as long as the survey agency finds that it is in the public interest and essential to assuring ICF services for eligible individuals in the community.

§ 442.317 Arrangements with outside resources.

(a) If the ICF does not employ a qualified professional to furnish a required institutional service, it must have in effect a written agreement with a qualified professional outside the ICF to furnish the required service.

(b) The agreement must—

(1) Contain the responsibilities, functions, objectives, and other terms agreed to by the ICF and the qualified professional; and

(2) Be signed by the administrator or his representative and by the qualified professional.

(c) The ICF must maintain effective arrangements with outside resources for promptly providing medial and remedical services required by a resident but not regularly provided within the ICF.

§ 442.318 Resident record system.

(a) The ICF must maintain an organized resident record system that contains a record for each resident.

(b) The ICF must make resident records available to staff directly involved with the resident and to appropriate representatives of the Medicaid agency.

(c) Each resident's record must contain—

(1) Identification information;

(2) Admission information, including the medical and social history of the resident;

(3) An overall plan of care as described in § 442.319;

(4) Copies of the initial and periodic examinations, evaluations, progress notes, all plans of care with subsequent changes, and discharge summaries;

(5) Description of treatments and services provided and medications administered; and

(6) All indications of illness or injury including the date, time, and action taken regarding each.

(d) The ICF must protect the resident records against destruction, loss, and unauthorized use.

(e) The ICF must keep a resident's record for at least 3 years after the date the resident is discharged.

§ 442.319 Overall plan of care.

The overall plan of care required by § 442.318 must—

(a) Set the goals to be accomplished by the resident;

(b) Prescribe an integrated program of activities, therapies, and treatments designed to help each resident achieve his goals; and

(c) Indicate which professional service or individual is responsible for each service prescribed in the plan.

§ 442.320 Resident financial records.

(a) The ICF must maintain a current, written financial record for each resident that includes written receipts for—

(1) All personal possessions and funds received by or deposited with the ICF; and

(2) All disbursements made to or for the resident.

(b) The financial record must be available to the resident and his family.

SAFETY STANDARDS

§ 442.321 Fire protection.

(a) Except as provided in § 442.323 and paragraph (b) of this section, the ICF must meet the applicable provisions of the 1985 edition of the Life Safety Code of the National Fire Protection Association which is incorporated by reference.[1]

(b) If the Secretary finds that the State has a fire and safety code imposed by State law that adequately protects residents in ICF's, the State survey agency may apply the State code for the purposes of Medicaid certification instead of the Life Safety Code.

(c) Any facility that on November 26, 1982 complies with the requirements of the 1967 edition of the Life Safety Code, or, on May 9, 1988, complies with the requirements of the 1981 edition of the Life Safety Code, with or without waivers, will be considered to be in compliance with this standard as long as the facility continues to remain in compliance with that edition of the Code.

[43 FR 45233, Sept. 29, 1978, as amended at 47 FR 47393, Oct. 26, 1982; 51 FR 23545, June 30, 1986; 53 FR 11509, Apr. 7, 1988]

§ 442.323 Fire protection: Waivers.

The State survey agency may waive specific provisions of the Life Safety Code required by § 442.321, for so long as it considers appropriate, if—

(a) The waiver would not adversely affect the health and safety of the residents;

(b) Rigid application of specific provisions of the Life Safety Code would result in unreasonable hardship for the ICF; and

(c) The waiver is granted in accordance with guidelines issued by HCFA.

(d)(1) Any facility of two or more stories that is not of fire resistive construction and is participating on the basis of a waiver of construction type or height may not house blind, nonambulatory, or physically handicapped patients above the street-level floor unless the facility—

(i) Is one of the following construction types (as defined in the Life Safety Code):

(A) Type II (1, 1, 1)—protected noncombustible.

(B) Fully sprinklered Type II (0, 0, 0)—non-combustible.

(C) Fully sprinklered Type III (2, 1, 1)—protected ordinary.

(D) Fully sprinklered Type V (1, 1, 1)—protected wood frame; or

(ii) Achieves a passing score on the Fire Safety Evaluation System (FSES).

[53 FR 11509, Apr. 7, 1988]

ENVIRONMENTAL AND SANITATION STANDARDS

§ 442.324 Resident living areas.

The ICF must—

(a) Design and equip the resident living areas for the comfort and privacy of each resident; and

(b) Have handrails that are firmly attached to the walls in all corridors used by residents.

§ 442.325 Residents' rooms.

(a) Each resident room must—

(1) Be equipped with or conveniently located near toilet and bathing facilities;

(2) Be at or above grade level;

(3) Contain a suitable bed for each resident and other appropriate furniture;

(4) Have closet space that provides security and privacy for clothing and personal belongings;

(5) Contain no more than four beds;

(6) Measure at least 100 square feet for a single-resident room or 80 square feet for each resident for a multiresident room; and

(7) Be equipped with a device for calling the staff member on duty.

(b) For an existing building, the State survey agency may waive the space and occupancy requirements of paragraphs (a) (5) and (6) of this section for as long as it is considered appropriate if it finds that—

(1) The requirements would result in unreasonable hardship on the ICF if strictly enforced; and

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[1] See footnote to § 405.1134(a) of this chapter.

(2) The waiver serves the particular needs of the residents and does not adversely affect their health and safety.

§ 442.326 Bathroom facilities.

The ICF must—

(a) Have toilet and bathing facilities that are located in or near residents' rooms and are appropriate in number, size, and design to meet the needs of the residents;

(b) Provide an adequate supply of hot water at all times for resident use; and

(c) Have plumbing fixtures with control valves that automatically regulate the temperature of the hot water used by residents.

§ 442.327 Linen supplies.

The ICF must have available at all times enough linen for the proper care and comfort of the residents and have clean linen on each bed.

§ 442.328 Therapy and isolation areas.

(a) The ICF's therapy area must be of sufficient size and appropriate design to—

(1) Accommodate the necessary equipment;

(2) Conduct an examination; and

(3) Provide treatment.

(b) The ICF must make provision for isolating residents with infectious diseases.

§ 442.329 Dining, recreation, and social rooms.

(a) The ICF must provide one or more areas, not used for corridor traffic, for dining, recreation, and social activities.

(b) A multipurpose room may be used if it is large enough to accommodate all of the activities without their interfering with each other.

§ 442.330 Building accessibility and use.

(a) The ICF must—

(1) Be accessible to and usable by all residents, personnel, and the public, including individuals with disabilities; and

(2) Meet the requirements of American National Standards Institute (ANSI) standard No. A117.1 (1961), American standard specifications for making building and facilities accessible to and usable by the physically handicapped.

(b) The State survey agency may waive, for as long as it considers appropriate, provisions of ANSI standard No. A117.1 (1961) if—

(1) The construction plans for the ICF or a part of it were approved and stamped by the responsible State agency before March 18, 1974;

(2) The provisions would result in unreasonable hardship on the ICF if strictly enforced; and

(3) The waiver does not adversely affect the health and safety of the residents.

MEAL SERVICE

§ 442.331 Meal service.

The ICF must—

(a) Serve at least three meals or their equivalent each day at regular times, with not more than 14 hours between a substantial evening meal and breakfast;

(b) Procure, store, prepare, distribute, and serve all food under sanitary conditions; and

(c) Provide special eating equipment and utensils for residents who need them.

§ 442.332 Menu planning and supervision.

(a) The ICF must have a staff member trained or experienced in food management or nutrition who is responsible for—

(1) Planning menus that meet the nutritional needs of each resident, following the orders of the resident's physician and, to the extent medically possible, the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences (Recommended Dietary Allowances (8th ed., 1974) is available from the Printing and Publications Office, National Academy of Sciences, Washington, D.C. 20418); and

(2) Supervising the meal preparation and service to insure that the menu plan is followed.

(b) If the ICF has residents who require medically prescribed special diets, the ICF must—

(1) Have the menus for those residents planned by a professionally

qualified dietitian, or reviewed and approved by the attending physician; and

(2) Supervise the preparation and serving of meals to insure that the resident accepts the special diet.

(c) The ICF must keep for 30 days a record of each menu as served.

MEDICATIONS

§ 442.333 Licensed pharmacist.

The ICF must either—

(a) Employ a licensed pharmacist; or

(b) Have a formal arrangement with a licensed pharmacist to advise the ICF on ordering, storage, administration, disposal, and recordkeeping of drugs and biologicals.

§ 442.334 Orders for medications.

(a) The resident's attending or staff physician must order all medications for the resident.

(b) The order may be either oral or written.

(c) If the order is oral—

(1) The physician must give it only to a licensed nurse, pharmacist, or another physician; and

(2) The individual receiving the order must record and sign it immediately and have the attending physician sign it in a manner consistent with good medical practice.

§ 442.335 Methods to control medication dosage.

The ICF must have written policies and procedures for controlling medication dosage, by automatic stop orders or other methods, when the physician does not include in the order a specific limit on the time or number of doses. These procedures must include notice to the attending physician that the medication is being stopped as of a certain date or after a certain number of doses.

§ 442.336 Review of medications.

(a) A pharmacist must review medications monthly for each resident and notify the physician if changes are appropriate.

(b) The attending or staff physician must review the medications quarterly.

[43 FR 45233, Sept. 29, 1978, as amended at 52 FR 22645, June 15, 1987]

§ 442.337 Administering medications.

(a) Before administering any medication to a resident, a staff member must complete a State-approved training program in medication administration.

(b) The ICF may allow a resident to give himself a medication only if the attending physician gives permission.

HEALTH SERVICES

§ 442.338 Health services.

(a) The ICF must provide for each resident health services that—

(1) Meet the requirements of §§ 442.339 through 442.342; and

(2) Include treatment, medications, diet, and any other health service prescribed or planned for the resident.

(b) The ICF must provide these services 24 hours a day.

§ 442.339 Supervision.

(a) The ICF must have a registered nurse or a licensed practical or vocational nurse to supervise the ICF's health services full time, 7 days a week, on the day shift.

(b) The nurse must have a current license to practice in the State.

(c) If the ICF employs a licensed practical or vocational nurse to supervise health services, the ICF must have a formal contract with a registered nurse to consult with the licensed practical or vocational nurse at regular intervals, but not less than 4 hours each week.

(d) To be qualified to serve as a health services supervisor, a licensed practical or vocational nurse must—

(1) Be a graduate of a State-approved school of practical nursing;

(2) Have education or other training that the State authority responsible for licensing practical nurses considers equal to graduation from a State-approved school of practical nursing; or

(3) Have passed the Public Health Service examination for waivered licensed practical or vocational nurses.

(e) The ICF may employ as charge nurse an individual who is licensed by the State in a category other than registered nurse or licensed practical or vocational nurse if—

(1) The individual has completed a training program to get the license that included at least the same number of classroom and practice hours in all nursing subjects as in the program of a State-approved school of practical or vocational nursing; and

(2) The State agency responsible for licensing the individual submits a report to the Medicaid agency comparing State licensed practical nurse or vocational nurse course requirements with those for the program completed by the individual.

§ 442.340 24-hour staffing.

The ICF must have responsible staff members on duty and awake 24 hours a day to take prompt, appropriate action in case of injury, illness, fire, or other emergency.

§ 442.341 Individual health care plan.

(a) Appropriate staff must develop and implement a written health care plan for each resident according to the instructions of the attending or staff physician.

(b) The plan must be reviewed and revised as needed but at least quarterly.

§ 442.342 Nursing care.

The ICF must provide nursing care for each resident as needed, including restorative nursing care that enables each resident to achieve and maintain the highest possible degree of function, self-care, and independence.

OTHER SERVICES

§ 442.343 Rehabilitative services.

(a) The ICF must provide rehabilitative services for each resident as needed.

(b) The ICF must either provide these services itself or arrange for them with qualified outside resources.

(c) The rehabilitative services must be designed to—

(1) Maintain and improve the resident's ability to function independently;

(2) Prevent, as much as possible, advancement of progressive disabilities; and

(3) Restore maximum function.

(d) The rehabilitative services must be provided by—

(1) Qualified therapists or qualified assistants, as defined in 42 CFR 405.1101 (m), (n), (q), (r), and (t), in accordance with accepted professional practices; or

(2) Other supportive personnel under appropriate supervision.

(e) The rehabilitative services must be provided under a written plan of care that is—

(1) Developed in consultation with the attending physician and, if necessary, an appropriate therapist; and

(2) Based on the attending physician's orders and an assessment of the resident's needs.

(f) The resident's progress under the plan must be reviewed regularly and the plan must be changed as necessary.

§ 442.344 Social services.

(a) The ICF must provide social services for each resident as needed.

(b) The ICF must either provide these services itself or arrange for them with qualified outside resources.

(c) The ICF must designate one staff member, qualified by training or experience, to be responsible for—

(1) Arranging for social services; and

(2) Integrating social services with other elements of the plan of care.

(d) These services must be provided under a written plan of care that is—

(1) Placed in the resident's record; and

(2) Evaluated periodically in conjunction with the resident's overall plan of care.

§ 442.345 Activities program.

The ICF must—

(a) Provide an activities program designed to encourage each resident to maintain normal activity and to return to self-care;

(b) Designate one staff member, qualified by training or experience in directing group activity, to be responsible for it;

(c) Have a plan for independent and group activities for each resident that is—

(1) Developed according to his needs and interests;

(2) Incorporated in his overall plan of care;

(3) Reviewed, with his participation, at least quarterly; and

(4) Changed as needed.

(d) Provide adequate recreation areas with sufficient equipment and materials to support the program.

§ 442.346 Physician services.

(a) The ICF must have policies and procedures to insure that the health care of each resident is under the continuing supervision of a physician.

(b) The physician must see the resident whenever necessary but at least once every 60 days unless the physician decides that this frequency is unnecessary and records the reasons for that decision.

Subpart G—[Reserved]

Effective Date Note: At 53 FR 20496, June 3, 1988, Subpart G was removed, effective October 3, 1988.

PART 447—PAYMENTS FOR SERVICES

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AUTHORITY: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

SOURCE: 43 FR 45253, Sept. 29, 1978, unless otherwise noted.

Subpart A—Payments: General Provisions

§ 447.1 Purpose.

This subpart prescribes State plan requirements, FFP limitations and procedures concerning payments made by State Medicaid agencies for Medicaid services.

§ 447.10 Prohibition against reassignment of provider claims.

(a) *Basis and purpose.* This section implements section 1902(a)(32) of the Act which prohibits State payments for Medicaid services to anyone other than a provider or recipient, except in specified circumstances; and implements, in part, section 1902(a)(43) concerning payments to physicians for laboratory services (see also § 447.342).

(b) *Definitions.* For purposes of this section:

Facility means an institution that furnishes health care services to inpatients.

Factor means an individual or an organization, such as a collection agency or service bureau, that advances money to a provider for accounts receivable that the provider has assigned, sold or transferred to the individual organization for an added fee or a deduction of a portion of the accounts receivable. Factor does not include a business representative as described in paragraph (f) of this section.

Organized health care delivery system means a public or private organization for delivering health services. It includes, but is not limited to, a clinic, a group practice prepaid capitation plan, and a health maintenance organization.

(c) *State plan requirements.* A State plan must provide that the requirements of paragraphs (d) through (h) of this section are met.

(d) *Who may receive payment.* Payment may be made only—

(1) To the provider; or

(2) To the recipient if he is a noncash recipient eligible to receive the payment under § 447.25; or

(3) In accordance with paragraphs (e), (f), and (g) of this section.

(e) *Reassignments.* Payment may be made in accordance with a reassignment from the provider to a government agency or reassignment by a court order.

(f) *Business agents.* Payment may be made to a business agent, such as a billing service or an accounting firm, that furnishes statements and receives payments in the name of the provider, if the agent's compensation for this service is—

(1) Related to the cost of processing the billing;

(2) Not related on a percentage or other basis to the amount that is billed or collected; and

(3) Not dependent upon the collection of the payment.

(g) *Individual practitioners.* Payment may be made to—

(1) A physician who bills for outside laboratory services that the physician orders and pays for, but that he or she did not personally perform or super-

vise, or which were not performed or supervised by another physician with whom he or she shares a practice.

(2) The employer of the practitioner, if the practitioner is required as a condition of employment to turn over his fees to the employer;

(3) The facility in which the service is provided, if the practitioner has a contract under which the facility submits the claim; or

(4) A foundation, plan, or similar organization operating an organized health care delivery system, if the practitioner has a contract under which the organization submits the claim.

(h) *Prohibition of payment to factors.* Payment for any service furnished to a recipient by a provider may not be made to or through a factor, either directly or by power of attorney.

[43 FR 45253, Sept. 29, 1978, as amended at 46 FR 42672, Aug. 24, 1981]

§ 447.15 Acceptance of State payment as payment in full.

A State plan must provide that the Medicaid agency must limit participation in the Medicaid program to providers who accept, as payment in full, the amounts paid by the agency plus any deductible, coinsurance or copayment required by the plan to be paid by the individual. However, the provider may not deny services to any eligible individual on account of the individual's inability to pay the cost sharing amount imposed by the plan in accordance with § 431.55(g) or § 447.53. The previous sentence does not apply to an individual who is able to pay. An individual's inability to pay does not eliminate his or her liability for the cost sharing charge.

[50 FR 23013, May 30, 1985]

§ 447.25 Direct payments to certain recipients for physicians' or dentists' services.

(a) *Basis and purpose.* This section implements section 1905(a) of the Act by prescribing requirements applicable to States making direct payments to certain recipients for physicians' or dentists' services.

(b) *State plan requirements.* Except for groups specified in paragraph (c) of this section, a State may make direct payments to recipients for physicians' or dentists' services. If it does so, the State plan must—

(1) Provide for direct payments; and

(2) Specify the conditions under which payments are made.

(c) *Federal financial participation.* No FFP is available in expenditures for direct payment for physicians' or dentists' services to any recipient—

(1) Who is receiving assistance under the State's approved plan under title I, IV-A, X, XIV or XVI (AABD) of the Act; or

(2) To whom supplemental security benefits are being paid under title XVI of the Act; or

(3) Who is receiving or eligible for a State supplementary payment or would be eligible if he were not in a medical institution, and who is eligible for Medicaid as a categorically needy recipient.

(d) *Federal requirements.* (1) Direct payments to recipients under this section are an alternative to payments directly to providers and are subject to the same conditions; for example, the State's reasonable charge schedules are applicable.

(2) Direct payments must be supported by providers' bills for services.

§ 447.30 Withholding the Federal share of payments to Medicaid providers to recover Medicare overpayments.

(a) *Basis and purpose.* This section implements section 1914 of the Act, which provides for withholding the Federal share of Medicaid payments to a provider if the provider has not arranged to repay Medicare overpayments or has failed to provide information to determine the amount of the overpayments. The intent of the statute and regulations is to facilitate the recovery of Medicare overpayments. The provision enables recovery of overpayments when institutions have reduced participation in Medicare or when physicians and suppliers have submitted few or no claims under Medicare, thus not receiving enough in Medicare reimbursement to permit offset of the overpayment.

(b) *When withholding occurs.* The Federal share of Medicaid payments may be withheld from any provider specified in paragraph (c) of this section to recover Medicare overpayments that HCFA has been unable to collect if the provider participates in Medicaid and—

(1) The provider has not made arrangements satisfactory to HCFA to repay the Medicare overpayment; or

(2) HCFA has been unable to collect information from the provider to determine the existence or amount of Medicare overpayment.

(c) The Federal share of Medicaid payments may be withheld with respect to the following providers:

(1) An institutional provider that has or previously had in effect a Medicare provider agreement under section 1866 of the Act; and

(2) A Medicaid provider who has previously accepted Medicare payment on the basis of an assignment under section 1842(b)(3)(B)(ii) of the Act; and during the 12 month period preceding the quarter in which the Federal share is to be withheld for a Medicare overpayment, submitted no claims under Medicare or submitted claims which total less than the amount of overpayment.

(d) *Order to reduce State payment.*

(1) HCFA may, at its discretion, issue an order to the Medicaid agency of any State that is using the provider's services, to reduce its payment to the provider by the amount specified in paragraph (f) of this section.

(2) The order to reduce payment to the provider will remain in effect until—

(i) The Medicaid agency determines that the overpayment has been completely recovered; or

(ii) HCFA terminates the order.

(3) HCFA may withhold FFP from any State that does not comply with the order specified in paragraph (d)(1) of this section to reduce payment to the provider and claims FFP for the expenditure on its quarterly expenditure report.

(e) *Notice of withholding.* (1) Before the Federal share of payments may be withheld under this section, HCFA will notify the provider and the Medicaid agency of each State that HCFA believes may use the overpaid provider's services under Medicaid.

(2) The notice will include the instruction to reduce State payments, as provided under paragraph (d) of this section.

(3) HCFA will send the notice referred to in paragraph (e)(1) by certified mail, return receipt requested.

(4) Each Medicaid agency must identify the amount of payment due the provider under Medicaid and give that information to HCFA in the next quarterly expenditure report.

(5) The Medicaid agency may appeal any disallowance of FFP resulting from the withholding decision to the Grant Appeals Board, in accordance with 45 CFR Part 16.

(f) Amount to be withheld. HCFA may require the Medicaid agency to reduce the Federal share of its payment to the provider by the lesser of the following amounts.

(1) The Federal matching share of payments to the provider, or

(2) The total Medicare overpayment to the provider.

(g) *Effective date of withholding.* Withholding of payment will become effective no less than 60 days after the day on which the agency receives notice of withholding.

(h) *Duration of withholding.* No Federal funds are available in expenditures for services that are furnished by a provider specified in paragraph (c) of this section from the date on which the withholding becomes effective until the termination of withholding under paragraph (i) of this section.

(i) *Termination of withholding.*

(1) HCFA will terminate the order to reduce State payment if it determines that any of the following has occurred:

(i) The Medicare overpayment is completely recovered:

(ii) The institution or person makes an agreement satisfactory to HCFA to repay the overpayment; or

(iii) HCFA determines that there is no overpayment based on newly acquired evidence or a subsequent audit.

(2) HCFA will notify each State that previously received a notice ordering the withholding that the withholding has been terminated.

(j) *Procedures for restoring excess withholding.* If an amount ultimately determined to be in excess of the Medicare overpayment is withheld, HCFA will restore any excess funds withheld.

(k) *Recovery of funds from Medicaid agency.* A provider is not entitled to recover from the Medicaid agency the amount of payment withheld by the agency in accordance with a HCFA order issued under paragraph (d) of this section.

[50 FR 19688, May 10, 1985; 50 FR 23307, June 3, 1985]

§ 447.31 Withholding Medicare payments to recover Medicaid overpayments.

(a) *Basis and purpose.* Section 1885 of the Act provides authority for HCFA to withhold Medicare payments to a Medicaid provider in order to recover Medicaid overpayments to the provider. Section 405.375 of this chapter sets forth the Medicare rules implementing section 1885, and specifies under what circumstances withholding will occur and the providers that are subject to withholding. This section establishes the procedures that the Medicaid agency must follow when requesting that HCFA withhold Medicare payments.

(b) *Agency notice to providers.* (1) Before the agency requests recovery of a Medicaid overpayment through Medicare, the agency must send either or both of the following notices, in addition to that required under paragraph (b)(2) of this section, to the provider.

(i) Notice that—

(A) There has been an overpayment;

(B) Repayment is required; and

(C) The overpayment determination is subject to agency appeal procedures, but we may withhold Medicare payments while an appeal is in progress.

(ii) Notice that—

(A) Information is needed to determine the amount of overpayment if any; and

(B) The provider has at least 30 days in which to supply the information to the agency.

(2) Notice that, 30 days or later from the date of the notice, the agency intends to refer the case to HCFA for withholding of Medicare payments.

(3) The agency must send all notices to providers by certified mail, return receipt requested.

(c) *Documentation to be submitted to HCFA.* The agency must submit the following information or documentation to HCFA (unless otherwise specified) with the request for withholding of Medicare payments.

(1) A statement of the reason that withholding is requested.

(2) The amount of overpayment, type of overpayment, date the overpayment was determined, and the closing date of the pertinent cost reporting period (if applicable).

(3) The quarter in which the overpayment was reported on the quarterly expenditure report (Form HCFA 64).

(4) As needed, and upon request from HCFA, the names and addresses of the provider's officers and owners for each period that there is an outstanding overpayment.

(5) A statement of assurance that the State agency has met the notice requirements under paragraph (b) of this section.

(6) As needed, and upon request for HCFA, copies of notices (under paragraph (b) of this section), and reports of contact or attempted contact with the provider concerning the overpayment, including any reduction or suspension of Medicaid payments made with respect to that overpayment.

(7) A copy of the provider's agreement with the agency under § 431.107 of this chapter.

(d) *Notification to terminate withholding.* (1) If an agency has requested withholding under this section, it must notify HCFA if any of the following occurs:

(i) The Medicaid provider makes an agreement satisfactory to the agency to repay the overpayment;

(ii) The Medicaid overpayment is completely recovered; or

(iii) The agency determines that there is no overpayment, based on newly acquired evidence or subsequent audit.

(2) Upon receipt of notification from the State agency, HCFA will terminate withholding.

(e) *Accounting for returned overpayment.* The agency must treat as a recovered overpayment the amounts received from HCFA to offset Medicaid overpayments.

(f) *Procedures for restoring excess withholding.* The agency must establish procedures satisfactory to HCFA to assure the return to the provider of amounts withheld under this section that are ultimately determined to be in excess of overpayments. Those procedures are subject to HCFA review.

[50 FR 19689, May 10, 1985]

§ 447.35 Limits on FFP for capital expenditures.

(a) *Basis and purpose.* (1) Section 1122 of the Act provides for exclusion from FFP of expenses related to certain capital expenditures. The cost containment and quality control regulations of the Public Health Service (Part 100 of this title) concern agreements between the Secretary and the States under section 1122, procedures for reviewing proposed capital expenditures, and determinations by the Secretary as to allowability of expenses related to capital expenditures.

(2) This section identifies categories of expenses for which FFP is not available under Medicaid if a State has an agreement under section 1122 and the Secretary has determined under section 1122 and Part 100 that the expenses are not allowable.

(b) *FFP limits.* Except as provided in § 100.108(b) of this title, no FFP is available in expenses related to a capital expenditure if the Secretary determines that—

(1) The State designated planning agency had not been given timely written notice of a capital expenditure in accordance with § 100.106 of this title; or

(2) The planning agency has, under section 1122 and Part 100 of this title, submitted to the Secretary its finding that the proposed expenditure is not consistent with the standards, criteria or plans described in § 100.104(a)(2) of this title.

(c) *Expenses related to a capital expenditure.* Expenses related to a capital expenditure include the following, regardless of the manner in which the expenses are recorded in the provider's records and cost report:

(1) Depreciation.

(2) Interest on borrowed funds.

(3) A return on equity capital (in the case of proprietary facilities).

(4) Other costs of activities that are essential to the acquisition, improvement, modernization, expansion, or replacement of the plant, buildings, and equipment with respect to which the expenditure is made, including, but not limited to—

(i) Studies, surveys, designs, plans, working drawings, and specifications;

(ii) Transportation;

(iii) Installation and start-up expenses;

(iv) In-transit insurance;

(v) Costs of grading and paving;

(vi) Taxes assessed during the construction period;

(vii) Costs of demolishing or razing structures on land;

(viii) Title fees;

(ix) Permit and license fees;

(x) Broker commissions;

(xi) Architectural, legal, accounting, and appraisal fees; and

(xii) Interest, finance, or carrying charges on bonds, notes, and other costs incurred for borrowing funds.

(d) *FFP for costs of conformity determination.* FFP is available in expenditures for reasonable costs incurred by a provider to determine whether a proposed capital expenditure is in conformity with applicable standards, criteria, or plans for adequate health care resources in the area. However, no FFP is available if the provider makes the capital expenditure without the approval required by Part 100 of this title.

(e) *Exclusion of expenses related to capital expenditures: Payment on a reasonable cost or cost-related basis.* If payment is made on a reasonable cost or cost-related basis, expenses related to capital expenditures that are not available for FFP must be specifically excluded from allowable cost computations.

(f) *Exclusion of expenses related to capital expenditures: Payment on other than a reasonable cost or cost-related basis.* If payment is made on a per capita, fixed fee, negotiated rate, or any other basis (other than reasonable cost or cost-related), expenses related to capital expenditures that are not available for FFP must be excluded from the payment rate as follows:

(1) For a facility that participates in the Medicare program, the State shall—

(i) Compute the percentage difference between the Medicare allowable costs before and after the deduction of unallowed expenses; and

(ii) Reduce the Medicaid payment rate to the facility by that percentage.

(2) For a facility that does not participate in the Medicare program, the State must reduce the payment rate by an estimated amount. The estimate is based upon a comparative analysis of the facility's expenses related to capital expenditures as reflected in the facility's periodic financial statements. For example, the State may compute the percentage difference between the facility's expenses related to capital expenditures as recorded in its financial statements and those expenses less the amounts for which FFP is not available, and reduce the payment rate by that percentage.

(g) *Equivalent deduction if a facility is obtained by a lease.* If a person obtained by lease or comparable arrangement any facility, part of a facility, or equipment for a facility that would have been considered a capital expenditure if the person had purchased it—

(1) In determining payments for services furnished in that facility, an amount must be deducted from rental expense which is a reasonable equivalent of the amount that would have been excluded if the person had purchased the facility or equipment; and

(2) In computing the person's return on equity capital, any amount deposited under the terms of the lease or comparable arrangement must be deducted from that return.

(h) *Capital assets acquired by donation or exchange.* If a person acquired by donation or exchange any facility, part of a facility, or equipment for a facility that would have been considered a capital expenditure if the person had purchased it, the acquisition is treated as a capital expenditure for purposes of excluding expenses related to capital expenditures.

(i) *Reconsideration of FFP determination.* (1) Any person or State adversely affected by a determination by the Secretary under section 1122 of the Act, this subpart or Part 100 of this title may, within 6 months of the date of the determination, request the Secretary to reconsider the determination. A determination by the Secretary under section 1122 of the Act is not subject to administrative or judicial review.

(2) A State is also entitled upon request to receive a reconsideration of a disallowance under this subpart, in accordance with section 1116(d) of the Act and 45 CFR Part 16.

§ 447.40 Payments for reserving beds in institutions.

(a) The Medicaid agency may make payments to reserve a bed during a recipient's temporary absence from an inpatient facility, if—

(1) The State plan provides for such payments and specifies any limitations on the policy; and

(2) Absences for purposes other than required hospitalization (which cannot be anticipated and planned) are included in the patient's plan of care.

(b) An agency that pays for reserved beds in an inpatient facility may pay less for a reserved bed than an occupied bed if there is a cost differential between the two beds. (Section 1102 of the Act.)

[43 FR 45253, Sept. 29, 1978, as amended at 51 FR 24491, July 3, 1986]

§ 447.45 Timely claims payment.

(a) *Basis and purpose.* This section implements section 1902(a)(37) of the Act by specifying—

(1) State plan requirements for—

(i) Timely processing of claims for payment;

(ii) Prepayment and postpayment claims reviews; and

(2) Conditions under which the Administrator may grant waivers of the time requirements.

(b) *Definitions. Claim* means (1) a bill for services, (2) a line item of service, or (3) all services for one recipient within a bill.

Clean claim means one that can be processed without obtaining additional information from the provider of the service or from a third party. It includes a claim with errors originating in a State's claims system. It does not include a claim from a provider who is under investigation for fraud or abuse, or a claim under review for medical necessity.

A *shared health facility* means any arrangement in which—

(1) Two or more health care practitioners practice their professions at a common physical location;

(2) The practitioners share common waiting areas, examining rooms, treatment rooms, or other space, the services of supporting staff, or equipment;

(3) The practitioners have a person (who may himself be a practitioner)—

(i) Who is in charge of, controls, manages, or supervises substantial aspects of the arrangement or operation for the delivery of health or medical services at the common physical location other than the direct furnishing of professional health care services by the practitioners to their patients; or

(ii) Who makes available to the practitioners the services of supporting staff who are not employees of the practitioners; and

(iii) Who is compensated in whole or in part, for the use of the common physical location or related support services, on a basis related to amounts charged or collected for the services rendered or ordered at the location or on any basis clearly unrelated to the value of the services provided by the person; and

(4) At least one of the practitioners received payments on a fee-for-service basis under titles V, XVIII, and XIX in an amount exceeding $5,000 for any one month during the preceding 12 months or in an aggregate amount exceeding $40,000 during the preceding 12 months.

The term does not include a provider of services (as specified in § 489.2(b) of this chapter), a health maintenance organization (as defined in section 1301(a) of the Public Health Service Act), a hospital cooperative shared services organization meeting the requirements of section 501(e) of the Internal Revenue Code of 1954, or any public entity.

Third party is defined in § 433.135 of this chapter.

(c) *State plan requirements.* A State plan must (1) provide that the requirements of paragraphs (d), (e)(2), (f) and (g) of this section are met; and

(2) Specify the definition of a claim, as provided in paragraph (b) of this section, to be used in meeting the requirements for timely claims payment. The definition may vary by type of service (e.g., physician service, hospital service).

(d) *Timely processing of claims.* (1) The Medicaid agency must require providers to submit all claims no later than 12 months from the date of service.

(2) The agency must pay 90 percent of all clean claims from practitioners, who are in individual or group practice or who practice in shared health facilities, within 30 days of the date of receipt.

(3) The agency must pay 99 percent of all clean claims from practitioners, who are in individual or group practice or who practice in shared health facilities, within 90 days of the date of receipt.

(4) The agency must pay all other claims within 12 months of the date of receipt, except in the following circumstances:

(i) This time limitation does not apply to retroactive adjustments paid to providers who are reimbursed under a retrospective payment system, as defined in § 447.272 of this part.

(ii) If a claim for payment under Medicare has been filed in a timely manner, the agency may pay a Medicaid claim relating to the same services within 6 months after the agency or the provider receives notice of the disposition of the Medicare claim.

(iii) The time limitation does not apply to claims from providers under investigation for fraud or abuse.

(iv) The agency may make payments at any time in accordance with a court order, to carry out hearing decisions or agency corrective actions taken to resolve a dispute, or to extend the benefits of a hearing decision, corrective action, or court order to others in the same situation as those directly affected by it.

(5) The date of receipt is the date the agency receives the claim, as indicated by its date stamp on the claim.

(6) The date of payment is the date of the check or other form of payment.

(e) *Waivers.* (1) The Administrator may waive the requirements of paragraphs (d) (2) and (3) of this section upon request by an agency if he finds that the agency has shown good faith in trying to meet them. In deciding whether the agency has shown good faith, the Administrator will consider whether the agency has received an unusually high volume of claims which are not clean claims, and whether the agency is making diligent efforts to implement an automated claims processing and information retrieval system.

(2) The agency's request for a waiver must contain a written plan of correction specifying all steps it will take to meet the requirements of this section.

(3) The Administrator will review each case and if he approves a waiver, will specify its expiration date, based on the State's capability and efforts to meet the requirements of this section.

(f) *Prepayment and postpayment claims review.* (1) For all claims, the agency must conduct prepayment claims review consisting of—

(i) Verification that the recipient was included in the eligibility file and that the provider was authorized to furnish the service at the time the service was furnished;

(ii) Checks that the number of visits and services delivered are logically consistent with the recipient's characteristics and circumstances, such as type of illness, age, sex, service location.

(iii) Verification that the claim does not duplicate or conflict with one reviewed previously or currently being reviewed;

(iv) Verification that a payment does not exceed any reimbursement rates or limits in the State plan; and

(v) Checks for third party liability within the requirements of § 433.135 of this chapter.

(2) The agency must conduct postpayment claims review that meets the requirements of Parts 455 and 456 of this chapter, dealing with fraud and utilization control.

(g) *Reports.* The agency must provide any reports and documentation on compliance with this section that the Administrator may require.

(Secs. 1102 and 1902(a)(37) of the Social Security Act (42 U.S.C. 1302, 1396a(a)(37)))

[44 FR 30344, May 25, 1979]

COST SHARING

§ 447.50 Cost sharing: Basis and purpose.

(a) Section 1902(a)(14) of the Act permits States to require certain recipients to share some of the costs of Medicaid by imposing upon them such payments as enrollment fees, premiums, deductibles, coinsurance, co-payments, or similar cost sharing charges. For States that impose cost sharing payments, §§ 447.51 through 447.59 prescribe State plan requirements and options for cost sharing, specify the standards and conditions under which States may impose cost sharing, set forth minimum amounts and the methods for determining maximum amounts, and prescribe conditions for FFP that relate to cost sharing requirements.

ENROLLMENT FEE, PREMIUM OR SIMILAR COST SHARING CHARGE

§ 447.51 Requirements and options.

(a) The plan must provide that the Medicaid agency does not impose any enrollment fee, premium, or similar charge upon categorically needy individuals, as defined in §§ 435.4 and 436.3 of this subchapter, for any services available under the plan.

(b) The plan may impose an enrollment fee, premium, or similar charge on medically needy individuals, as defined in §§ 435.4 and 436.3 of this subchapter, for any services available under the plan.

(c) For each charge imposed under paragraph (b) of this section, the plan must specify—

(1) The amount of the charge;

(2) The period of liability for the charge; and

(3) The consequences for an individual who does not pay.

(d) The plan must provide that any charge imposed under paragraph (b) of this section is related to total gross family income as set forth under § 447.52.

§ 447.52 Minimum and maximum income-related charges.

For the purpose of relating the amount of an enrollment fee, premium, or similar charge to total gross family income, as required under § 447.51(d), the following rules apply:

(a) *Minimum charge.* A charge of at least $1.00 per month is imposed on each—

(1) One- or two-person family with monthly gross income of $150 or less;

(2) Three- or four-person family with monthly gross income of $300 or less; and

(3) Five- or more-person family with monthly gross income of $350 or less.

(b) *Maximum charge.* Any charge related to gross family income that is above the minimum listed in paragraph (a) of this section may not exceed the standards shown in the following table:

MAXIMUM MONTHLY CHARGE

Gross family income (per month)	Family size		
	1 or 2	3 or 4	5 or more
$150 or less	$1	$1	$1
$151 or $200	2	1	1
$201 to $250	3	1	1
$251 to $300	4	1	1
$301 to $350	5	2	1
$351 to $400	6	3	2
$401 to $450	7	4	3
$451 to $500	8	5	4
$501 to $550	9	6	5
$551 to $600	10	7	6
$601 to $650	11	8	7
$651 to $700	12	9	8
$701 to $750	13	10	9
$751 to $800	14	11	10
$801 to $850	15	12	11
$851 to $900	16	13	12
$901 to $950	17	14	13
$951 to $1,000	18	15	14
More than $1,000	19	16	15

(c) *Income-related charges.* The agency must impose an appropriately higher charge for each higher level of family income, within the maximum amounts specified in paragraph (b) of this section.

[43 FR 45253, Sept. 29, 1978, as amended at 45 FR 24889, Apr. 11, 1980]

DEDUCTIBLE, COINSURANCE, CO-PAYMENT OR SIMILAR COST-SHARING CHARGE

§ 447.53 Applicability; specification; multiple charges.

(a) *Basic requirements.* Except as specified in paragraph (b) of this section, the plan may impose a nominal deductible, coinsurance, copayment, or similar charge upon categorically and medically needy individuals for any service under the plan.

(b) *Exclusions from cost sharing.* Effective October 1, 1982, the plan may not provide for imposition of a deductible, coinsurance, copayment, or similar charge upon categorically or medically needy individuals (except as specified in paragraph (b)(6) of this section) for the following:

(1) *Children.* Services furnished to individuals under 18 years of age (and, at the option of the State, individuals under 21, 20, or 19 years of age, or any reasonable category of individuals 18 years of age or over but under 21) are excluded from cost sharing.

(2) *Pregnant women.* Services furnished to pregnant women if such services relate to the pregnancy, or to any other medical condition which may complicate the pregnancy are excluded from cost sharing obligations. These services include routine prenatal care, labor and delivery, routine post-partum care, and complications of pregnancy or delivery likely to affect the pregnancy, such as hypertension, diabetes, urinary tract infection, and services furnished during the postpartum period for conditions or complications related to the pregnancy. The postpartum period is the immediate postpartum period not to exceed six weeks. States may further exclude from cost sharing all services furnished to pregnant women if they desire.

(3) *Institutionalized individuals.* Services furnished to any individual who is an inpatient in a hospital, long-term care facility, or other medical institution if the individual is required (pursuant to § 435.725, § 435.733, § 435.832, or § 436.832), as a condition of receiving services in the institution, to spend all but a minimal amount of his income required for personal

needs, for medical care costs are excluded from cost sharing.

(4) *Emergency services.* Services provided in a hospital, clinic, office, or other facility that is equipped to furnish the required care, after the sudden onset of a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) that the absence of immediate medical attention could reasonably be expected to result in—

(i) Placing the patient's health in serious jeopardy;

(ii) Serious impairment to bodily functions; or

(iii) Serious dysfunction of any bodily organ or part.

(5) *Family planning.* Family planning services and supplies furnished to individuals of child-bearing age are excluded from cost sharing.

(6) *HMO Enrollees.* Services furnished by a health maintenance organization (HMO) to categorically needy individuals enrolled in the HMO are excluded from cost sharing. States may further exclude copayment charges for HMO services furnished to medically needy individuals.

(c) *Prohibition against multiple charges.* For any service, the plan may not impose more than one type of charge referred to in paragraph (a) of this section.

(d) *State plan specifications.* For each charge imposed under this section, the plan must specify—

(1) The service for which the charge is made;

(2) The amount of the charge;

(3) The basis for determining the charge;

(4) The basis for determining whether an individual is unable to pay the charge and the means by which such an individual will be identified to providers; and

(5) The procedures for implementing and enforcing the exclusions from cost sharing found in paragraph (b) of this section.

[43 FR 45253, Sept. 29, 1978, as amended at 47 FR 21051, May 17, 1982; 48 FR 5736, Jan. 8, 1983; 50 FR 23013, May 30, 1985]

§ 447.54 Maximum allowable charges.

(a) *Non-institutional services.* Except as specified in paragraph (b), for non-institutional services, the plan must provide that—

(1) Any deductible it imposes does not exceed $2.00 per month per family for each period of Medicaid eligibility. For example, if Medicaid eligibility is certified for a 3-month period, the maximum deductible which may be imposed on a family for that period of eligibility is $6.00;

(2) Any coinsurance rate it imposes does not exceed 5 percent of the payment the agency makes for the services; and

(3) Any co-payments it imposes do not exceed the amounts shown in the following table:

States payment for the service	Maximum copayment chargeable to recipient
$10 or less	$.50
$10.01 to $25	1.00
$25.01 to $50	2.00
$50.01 or more	3.00

(b) *Waiver of the requirement that cost sharing amounts be nominal.* Upon approval from HCFA, the requirement that cost sharing charges must be nominal may be waived, in accordance with section 431.55(g) for nonemergency services furnished in a hospital emergency room.

(c) *Institutional services.* For institutional services, the plan must provide that the maximum deductible, coinsurance or co-payment charge for each admission does not exceed 50 percent of the payment the agency makes for the first day of care in the institution.

(d) *Cumulative maximum.* The plan may provide for a cumulative maximum amount for all deductible, coinsurance or co-payment charges that it imposes on any family during a specified period of time.

[48 FR 5736, Jan. 8, 1983]

§ 447.55 Standard co-payment.

(a) The plan may provide for a standard, or fixed, co-payment amount for any service.

(b) This standard copayment amount for any service may be determined by applying the maximum copayment amounts specified in § 447.54 (a) and (b) to the agency's average or typical payment for that service. For example, if the agency's typical payment for prescribed drugs is $4 to $5 per prescription, the agency might set a standard copayment of $0.50 per prescription.

§ 447.56 Income-related charges.

Subject to the maximum allowable charges specified in § 447.54 (a) and (b), the plan may provide for income-related deductible, coinsurance or copayment charges. For example, an agency may impose a higher charge on medically needy recipients than it imposes upon categorically needy recipients.

§ 447.57 Restrictions on payments to providers.

(a) The plan must provide that the agency does not increase the payment it makes to any provider to offset uncollected amounts for deductibles, coinsurance, copayments or similar charges that the provider has waived or are uncollectable, except as permitted under paragraph (b) of this section.

(b) For those providers that the agency reimburses under Medicare reasonable cost reimbursement principles, in accordance with Subpart B of this part, an agency may increase its payment to offset uncollected deductible, coinsurance, copayment, or similar charges that are bad debts of providers.

§ 447.58 Payments to prepaid capitation organizations.

Except for HMO services subject to the co-payment exclusion in § 447.53(b)(6), if the agency contracts with a prepaid capitation organization that does not impose the agency's deductibles, coinsurance, co-payments or similar charges on its recipient members, the plan must provide that the agency calculates its payments to the organization as if those cost sharing charges were collected.

[48 FR 5736, Jan. 8, 1983]

FEDERAL FINANCIAL PARTICIPATION

§ 447.59 FFP: Conditions relating to cost sharing.

No FFP in the State's expenditures for services is available for—

(a) Any cost sharing amounts that recipients should have paid as enrollment fees, premiums, deductibles, coinsurance, copayments, or similar charges under §§ 447.50 through 447.58 (except for amounts that the agency pays as bad debts of providers under § 447.57); and

(b) Any amounts paid by the agency on behalf of ineligible individuals, whether or not the individual had paid any required premium or enrollment fee.

Subpart B—Payment Methods: General Provisions

§ 447.200 Basis and purpose.

This subpart prescribes State plan requirements for setting payment rates to implement, in part, section 1902(a)(30) of the Act, which requires that payments for services be consistent with efficiency, economy, and quality of care.

[46 FR 48560, Oct. 1, 1981]

§ 447.201 State plan requirements.

(a) A State plan must provide that the requirements in this subpart are met.

(b) The plan must describe the policy and the methods to be used in setting payment rates for each type of service included in the State's Medicaid program.

§ 447.202 Audits.

The Medicaid agency must assure appropriate audit of records if payment is based on costs of services or on a fee plus cost of materials.

§ 447.203 Documentation of payment rates.

(a) The agency must maintain documentation of payment rates and make it available to HHS upon request.

(b) The agency must record, in State manuals or other official files, the following information for increases in payment rates for individual practitioner services:

(1) An estimate of the percentile of the range of customary charges to which the revised payment structure equates and a description of the methods used to make the estimate.

(2) An estimate of the composite average percentage increase of the revised payment rates over the preceding rates.

§ 447.204 Encouragement of provider participation.

The agency's payments must be sufficient to enlist enough providers so that services under the plan are available to recipients at least to the extent that those services are available to the general population.

§ 447.205 Public notice of changes in Statewide methods and standards for setting payment rates.

(a) *When notice is required.* Except as specified in paragraph (b) of this section, the agency must provide public notice of any significant proposed change in its methods and standards for setting payment rates for services.

(b) *When notice is not required.* Notice is not required if—

(1) The change is being made to conform to Medicare methods or levels of reimbursement;

(2) The change is required by court order; or

(3) The change is based on changes in wholesalers' or manufacturers' prices of drugs or materials, if the agency's reimbursement system is based on material cost plus a professional fee.

(c) *Content of notice.* The notice must—

(1) Describe the proposed change in methods and standards;

(2) Give an estimate of any expected increase or decrease in annual aggregate expenditures;

(3) Explain why the agency is changing its methods and standards;

(4) Identify a local agency in each county (such as the social services agency or health department) where copies of the proposed changes are available for public review;

(5) Give an address where written comments may be sent and reviewed by the public; and

(6) If there are public hearings, give the location, date and time for hearings or tell how this information may be obtained.

(d) *Publication of notice.* The notice must—

(1) Be published before the proposed effective date of the change; and

(2) Appear as a public announcement in one of the following publications:

(i) A State register similar to the FEDERAL REGISTER.

(ii) The newspaper of widest circulation in each city with a population of 50,000 or more.

(iii) The newspaper of widest circulation in the State, if there is no city with a population of 50,000 or more.

[46 FR 58680, Dec. 3, 1981; 47 FR 8567, Mar. 1, 1982, as amended at 48 FR 56057, Dec. 19, 1983]

Subpart C—Payment for Inpatient Hospital and Long-Term Care Facility Services

SOURCE: 46 FR 47971, Sept. 30, 1981, unless otherwise noted.

§ 447.250 Basis and purpose.

(a) This subpart implements section 1902(a)(13)(A) of the Act, which requires that the State plan provide for payment for hospital and long-term care facility services through the use of rates that the State finds, and makes assurances satisfactory to the Secretary, are reasonable and adequate to meet the costs that must be incurred by efficiently and economically operated facilities to provide services in conformity with State and Federal laws, regulations, and quality and safety standards.

(b) Section 447.253(a)(2) implements section 1902(a)(30) of the Act, which requires that payments be consistent with efficiency, economy, and quality of care;

(c) Section 447.271 implements section 1903(i)(3) of the Act, which requires that payments for inpatient hospital services not exceed the hospital's customary charges.

(d) Section 447.280 implements section 1913(b) of the Act, which concerns reimbursement for long-term care services furnished by swing-bed hospitals.

[48 FR 56057, Dec. 19, 1983]

PAYMENT RATES

§ 447.251 Definitions.

For the purposes of this subpart—

Long-term care facility services means skilled nursing facility (SNF) services and intermediate care facility (ICF) services, including intermediate care facility services for the mentally retarded (ICF/MR).

Provider means an institution that furnishes inpatient hospital services or an institution that furnishes long-term care facility services.

[46 FR 47971, Sept. 30, 1981; 46 FR 54743, Nov. 4, 1981]

§ 447.252 State plan requirements.

(a) The plan must provide that the requirements of this subpart are met.

(b) The plan must specify comprehensively the methods and standards used by the agency to set payment rates in a manner consistent with § 430.10 of this chapter.

(c) If the agency chooses to apply the cost limits established under Medicare (see § 413.30 of this chapter) on an individual provider basis, the plan must specify this requirement.

(Approved by the Office of Management and Budget under control number 0938-0193)

[48 FR 56058, Dec. 19, 1983, as amended at 51 FR 34833, Sept. 30, 1986]

§ 447.253 Other requirements.

(a) *State assurances.* In order to receive HCFA approval of a State plan change in payment methods and standards, the Medicaid agency must make assurances satisfactory to HCFA that the requirements set forth in paragraphs (b) through (g) of this section are being met, must submit the related information required by § 447.255 of this subpart, and must comply with all other requirements of this subpart.

(b) *Findings.* Whenever the Medicaid agency makes a change in its methods and standards, but not less often than annually, the agency must make the following findings:

(1) *Payment rates.* (i) The Medicaid agency pays for inpatient hospital services and long-term care facility services through the use of rates that are reasonable and adequate to meet the costs that must be incurred by efficiently and economically operated providers to provide services in conformity with applicable State and Federal laws, regulations, and quality and safety standards.

(ii) With respect to inpatient hospital services—

(A) The methods and standards used to determine payment rates take into account the situation of hospitals which serve a disproportionate number of low income patients with special needs;

(B) If a State elects in its State plan to cover inappropriate level of care services (that is, services furnished to hospital inpatients who require a lower covered level of care such as skilled nursing or intermediate care services) under conditions similar to those described in section 1861(v)(1)(G) of the Act, the methods and standards used to determine payment rates must specify that the payments for this type of care must be made at rates lower than those for inpatient hospital level of care services, reflecting the level of care actually received, in a manner consistent with section 1861(v)(1)(G) of the Act; and

(C) The payment rates are adequate to assure that recipients have reasonable access, taking into account geographic location and reasonable travel time, to inpatient hospital services of adequate quality.

(2) *Upper payment limits.* The agency's proposed payment rate will not exceed the upper payment limits as specified in § 447.272.

(c) *Provider appeals.* The Medicaid agency must provide an appeals or exception procedure that allows individual providers an opportunity to submit additional evidence and receive prompt administrative review, with respect to such issues as the agency determines appropriate, of payment rates.

(d) *Uniform cost reporting.* The Medicaid agency must provide for the filing of uniform cost reports by each participating provider.

(e) *Audit requirements.* The Medicaid agency must provide for periodic audits of the financial and statistical records of participating providers.

(f) *Public notice.* The Medicaid agency must provide that it has complied with the public notice requirements in § 447.205 of this part when it is proposing significant changes to its methods or standards for setting payment rates for inpatient hospital or LTC facility services.

(g) *Rates paid.* The Medicaid agency must pay for inpatient hospital and long term care services using rates determined in accordance with methods and standards specified in an approved State plan.

[48 FR 56057, Dec. 19, 1983, as amended at 52 FR 28147, July 28, 1987]

EDITORIAL NOTE: At 52 FR 28147, July 28, 1987, § 447.253 was amended, paragraph (b) contains information collection requirements which will not become effective until approval has been obtained from the Office of Management and Budget. HCFA will publish a notice in the FEDERAL REGISTER once approval has been obtained.

§ 447.255 Related information.

The Medicaid agency must submit, with the assurances described in § 447.253(a), the following information:

(a) The amount of the estimated average proposed payment rate for each type of provider (hospital, SNF, ICF, or ICF/MR), and the amount by which that estimated average rate increased or decreased relative to the average payment rate in effect for each type of provider for the immediately preceding rate period;

(b) An estimate of the short-term and, to the extent feasible, long-term effect the change in the estimated average rate will have on—

(1) The availability of services on a Statewide and geographic area basis;

(2) The type of care furnished;

(3) The extent of provider participation; and

(4) The degree to which costs are covered in hospitals that serve a disproportionate number of low income patients with special needs.

[48 FR 56058, Dec. 19, 1983]

§ 447.256 Procedures for HCFA action on assurances and State plan amendments.

(a) *Criteria for approval.* (1) HCFA approval action on State plans and State plan amendments, is taken in accordance with Subpart B of Part 430 of this chapter and sections 1116, 1902(b) and 1915(f) of the Act.

(2) In the case of State plan and plan amendment changes in payment methods and standards, HCFA bases its approval on the acceptability of the Medicaid agency's assurances that the requirements of § 447.253 have been met, and the State's compliance with the other requirements of this subpart.

(b) *Time limit.* HCFA will send a notice to the agency of its determination as to whether the assurances regarding a State plan amendment are acceptable within 90 days of the date HCFA receives the assurances described in § 447.253, and the related information described in § 447.255 of this subpart. If HCFA does not send a notice to the agency of its determination within this time limit and the provisions in paragraph (a) of this section are met, the assurances and/or the State plan amendment will be deemed accepted and approved.

(c) *Effective date.* A State plan amendment that is approved will become effective not earlier than the first day of the calendar quarter in which an approvable amendment is submitted in accordance with § 430.20 of this chapter and 447.253.

[48 FR 56058, Dec. 19, 1983, as amended at 52 FR 28147, July 28, 1987]

FEDERAL FINANCIAL PARTICIPATION

§ 447.257 FFP: Conditions relating to institutional reimbursement.

FFP is not available for a State's expenditures for hospital inpatient or long-term care facility services that are in excess of the amounts allowable under this subpart.

[52 FR 28147, July 28, 1987]

UPPER LIMITS

§ 447.271 Upper limits based on customary charges.

(a) Except as provided in paragraph (b) of this section, the agency may not pay a provider more for inpatient hospital services under Medicaid than the provider's customary charges to the general public for the services.

(b) The agency may pay a public provider that provides services free or at a nominal charge at the same rate that would be used if the provider's charges were equal to or greater than its costs.

§ 447.272 Application of upper payment limits.

(a) *General rule.* Except as provided in paragraph (c) of this section, aggregate payments by an agency to each group of health care facilities (that is, hospitals, SNFs, ICFs, or ICFs for the mentally retarded (ICFs/MR)) may not exceed the amount that can reasonably be estimated would have been paid for those services under Medicare payment principles.

(b) *State operated facilities.* In addition to meeting the requirement of paragraph (a) of this section, aggregate payments to each group of State-operated facilities (that is, hospitals, SNFs, ICFs, or ICFs/MR) may not exceed the amount that can reasonably be estimated would have been paid under Medicare payment principles.

(c) *Exception.* The upper payment limitation established under paragraphs (a) and (b) of this section does not apply to payment adjustments made under a State plan to hospitals found to serve a disproportionate number of low income patients with special needs, as provided in § 447.253(b)(1)(ii)(A).

[52 FR 28147, July 28, 1987]

SWING-BED HOSPITALS

§ 447.280 Hospital providers of SNF and ICF services (swing-bed hospitals).

(a) *General rule.* If the State plan provides for SNF or ICF services furnished by a swing-bed hospital, as specified in §§ 440.40(a) and 440.150(f) of this chapter, the methods and standards used to determine payment rates for routine SNF or ICF services must—

(1) Provide for payment at the average rate per patient day paid to SNFs or ICFs, other than ICFs/MR, as applicable, for routine services furnished during the previous calendar year; or

(2) Meet the State plan and payment requirements described in this subpart, as applicable.

(b) *Application of the rule.* The payment methodology used by a State to set payment rates for routine SNF or ICF services must apply to all swing-bed hospitals in the State.

[52 FR 28148, July 28, 1987]

Subpart D—Payment Methods for Other Institutional and Noninstitutional Services

SOURCE: 43 FR 45253, Sept. 29, 1978, unless otherwise noted. Redesignated at 46 FR 47973, Sept. 30, 1981.

§ 447.300 Basis and purpose.

In this subpart, §§ 447.302 through 447.334 and 447.361 implement section 1902(a)(30) of the Act, which requires that payments be consistent with efficiency, economy and quality of care. Section 447.342 of this subpart implements section 1902(a)(43) of the Act, which permits the State plan to provide for payment to a physician for laboratory services which the physician did not personally perform or supervise. Section 447.371 implements section 1902(a)(13)(F) of the Act, which requires that the State plan provide for payment for rural health clinic services in accordance with regulations prescribed by the Secretary.

[46 FR 48560, Oct. 1, 1981]

§ 447.301 Definitions.

For the purposes of this subpart—

Brand name means any registered trade name commonly used to identify a drug.

Estimated acquisition cost means the agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers.

Multiple source drug means a drug marketed or sold by two or more manufacturers or labelers or a drug marketed or sold by the same manufacturer or labeler under two or more different proprietary names or both under a proprietary name and without such a name.

[52 FR 28657, July 31, 1987]

§ 447.302 State plan requirements.

A State plan must provide that the requirements of this subpart are met.

[46 FR 48560, Oct. 1, 1981]

§ 447.304 Adherence to upper limits; FFP.

(a) The Medicaid agency must not pay more than the upper limits described in this subpart.

(b) In the case of payments made under the plan for deductibles and coinsurance payable on an assigned Medicare claim for noninstitutional services, those payments may be made only up to the reasonable charge under Medicare.

(c) FFP is available in expenditures for payments for services that do not exceed the upper limits.

NOTE: The Secretary may waive any limitation on reimbursement imposed by Subpart D of this part for experiments conducted under section 402 of Pub. L. 90-428, Incentives for Economy Experimentation, as amended by section 222(b) of Pub. L. 92-603, and under section 222(a) of Pub. L. 92-603.

[46 FR 48560, Oct. 1, 1981; 46 FR 54744, Nov. 4, 1981]

OUTPATIENT HOSPITAL AND CLINIC SERVICES

§ 447.321 Outpatient hospital services and clinic services: Upper limits of payment.

(a) *General rule.* FFP is not available for any payment that exceeds the amount that would be payable to providers under comparable circumstances under Medicare.

(b) *Application of the rule.* Payments by an agency for outpatient hospital services may not exceed the total payments received by all providers from beneficiaries and carriers or intermediaries for providing comparable services under comparable circumstances under Medicare.

[52 FR 28148, July 28, 1987]

OTHER INPATIENT AND OUTPATIENT FACILITIES

§ 447.325 Other inpatient and outpatient facility services: Upper limits of payment.

The agency may pay the customary charges of the provider but must not pay more than the prevailing charges in the locality for comparable services under comparable circumstances.

DRUGS

§ 447.331 Drugs: Aggregate upper limits of payment.

(a) *Multiple source drugs.* Except for brand name drugs that are certified in accordance with paragraph (c) of this section, the agency payment for multiple source drugs must not exceed, the amount that would result from the application of the specific limits established in accordance with § 447.332. If a specific limit has not been established under § 447.332, then the rule for "other drugs" set forth in paragraph (b) applies.

(b) *Other drugs.* The agency payments for brand name drugs certified in accordance with paragraph (c) of this section and drugs other than multiple source drugs for which a specific limit has been established under § 447.332 must not exceed in the aggregate, payment levels that the agency has determined by applying the lower of the—

(1) Estimated acquisition costs plus reasonable dispensing fees established by the agency; or

(2) Providers' usual and customary charges to the general public.

(c) *Certification of brand name drugs.* (1) The upper limit for payment for multiple source drugs for which a specific limit has been established under § 447.332 does not apply if a physician certifies in his or her own handwriting that a specific brand is medically necessary for a particular recipient.

(2) The agency must decide what certification form and procedure are used.

(3) A checkoff box on a form is not acceptable but a notation like "brand necessary" is allowable.

(4) The agency may allow providers to keep the certification forms if the forms will be available for inspection by the agency or HHS.

[52 FR 28657, July 31, 1987]

§ 447.332 Upper limits for multiple source drugs.

(a) *Establishment and issuance of a listing.* (1) HCFA will establish listings that identify and set upper limits for multiple source drugs that meet the following requirements:

(i) All of the formulations of the drug approved by the Food and Drug Administration (FDA) have been evaluated as therapeutically equivalent in the most current edition of their publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (including supplements or in successor publications).

(ii) At least three suppliers list the drug (which has been classified by the FDA as category "A" in its publication, *Approved Drug Products with Therapeutic Equivalence Evaluations,* including supplements or in successor publications) based on all listings contained in current editions (or updates) of published compendia of cost information for drugs available for sale nationally.

(2) HCFA publishes the list of multiple source drugs for which upper limits have been established and any revisions to the list in Medicaid program instructions.

(3) HCFA will identify the sources used in compiling these lists.

(b) *Specific upper limits.* The agency's payments for multiple source drugs identified and listed in accordance with paragraph (a) of this section must not exceed, in the aggregate, payment levels determined by applying for each drug entity a reasonable dispensing fee established by the agency plus an amount established by HCFA that is equal to 150 percent of the published price for the least costly therapeutic equivalent (using all available national compendia) that can be purchased by pharmacists in quantities of 100 tablets or capsules (or, if the drug is not commonly available in quantities of 100, the package size commonly listed) or, in the case of liquids, the commonly listed size.

[52 FR 28658, July 31, 1987]

§ 447.333 State plan requirements, findings and assurances.

(a) *State plan.* The State plan must describe comprehensively the agency's payment methodology for prescription drugs.

(b) *Findings and assurances.* Upon proposing significant State plan changes in payments for prescription drugs, and at least annually for multiple source drugs and triennially for all other drugs, the agency must make the following findings and assurances:

(1) *Findings.* The agency must make the following separate and distinct findings:

(i) In the aggregate, its Medicaid expenditures for multiple source drugs, identified and listed in accordance with § 447.332(a) of this subpart, are in accordance with the upper limits specified in § 447.332(b) of this subpart; and

(ii) In the aggregate, its Medicaid expenditures for all other drugs are in accordance with § 447.331 of this subpart.

(2) *Assurances.* The agency must make assurances satisfactory to HCFA that the requirements set forth in §§ 447.331 and 447.332 concerning upper limits and in paragraph (b)(1) of this section concerning agency findings are met.

(c) *Recordkeeping.* The agency must maintain and make available to HCFA, upon request, data, mathematical or statistical computations, comparisons, and any other pertinent records to support its findings and assurances.

[52 FR 28658, July 31, 1987]

§ 447.334 Upper limits for drugs furnished as part of services.

The upper limits for payment for prescribed drugs in this subpart also apply to payment for drugs provided as part of skilled nursing facility services and intermediate care facility services and under prepaid capitation arrangements.

CLINICAL LABORATORY SERVICES

§ 447.342 Physician billing for clinical laboratory services.

(a) This section applies when a State plan provides for payments to physicians for clinical laboratory services.

(b) [Reserved]

(c) A state plan may provide for payment to a physician who bills for clinical laboratory services performed by an outside laboratory. Under these circumstances, the plan must provide that the agency will not pay the physician more than the amount that would be authorized under Medicare in accordance with § 405.515 (b), (c), and (d) of this chapter.

[46 FR 48560, Oct. 1, 1981]

PREPAID CAPITATION PLANS

§ 447.361 Upper limits of payment: Risk contract.

Under a risk contract, Medicaid payments to the contractor, for a defined scope of services to be furnished to a defined number of recipients, may not exceed the cost to the agency of providing those same services on a fee-for-service basis, to an actuarially equivalent nonenrolled population group.

[48 FR 54025, Nov. 30, 1983]

§ 447.362 Upper limits of payment: Nonrisk contract.

Under a nonrisk contract, Medicaid payments to the contractor may not exceed—

(a) What Medicaid would have paid, on a fee-for-service basis, for the services actually furnished to recipients: plus

(b) The net savings of administrative costs the Medicaid agency achieves by contracting with the plan instead of purchasing the services on a fee-for-service basis.

[48 FR 54025, Nov. 30, 1983]

RURAL HEALTH CLINIC SERVICES

§ 447.371 Services furnished by rural health clinics.

The agency must pay for rural health clinic services, as defined in § 440.20(b) of this subchapter, and for other ambulatory services furnished by a rural health clinic, as defined in § 440.20(c) of this subchapter, as follows:

(a) For provider clinics, the agency must pay the reasonable cost of rural health clinic services and other ambulatory services on the basis of the cost reimbursement principles in Part 413 of this chapter. For purposes of this section, a provider clinic is an integral part of a hospital, skilled nursing facility, or home health agency that is participating in Medicare and is licensed, governed, and supervised with other departments of the facility.

(b) For clinics other than provider clinics that do not offer any ambulatory services other than rural health clinic services, the agency must pay for rural health clinic services at the reasonable cost rate per visit determined by a Medicare carrier under §§ 405.2426 through 405.2429 of this chapter.

(c) For clinics other than provider clinics that do offer ambulatory services other than rural health clinic services, the agency must pay for the other ambulatory services by one of the following methods:

(1) The agency may pay for other ambulatory services and rural health clinic services at a single rate per visit that is based on the cost of all services furnished by the clinic. The rate must be determined by a Medicare carrier under §§ 405.2426 through 405.2429 of this chapter.

(2) The agency may pay for other ambulatory services at a rate set for each service by the agency. The rate must not exceed the upper limits in this subpart. The agency must pay for rural health clinic services at the Medicare reimbursement rate per visit, as specified in § 405.2426 of this chapter.

(3) The agency may pay for dental services at a rate per visit that is based on the cost of dental services furnished by the clinic. The rate must be

determined by a Medicare carrier under §§ 405.2426 through 405.2429 of this chapter. The agency must pay for ambulatory services other than dental services under paragraph (c) (1) or (2) of this section.

(d) For purposes of paragraph (c) (1) and (3) of this section, "visit" means a face-to-face encounter between a clinic patient and any health professional whose services are reimbursed under the State plan. Encounters with more than one health professional, and multiple encounters with the same health professional, that take place on the same day and at a single location constitute a single visit, except when the patient, after the first encounter, suffers illness or injury requiring additional diagnosis or treatment.

[43 FR 45253, Sept. 29, 1978, as amended at 51 FR 34833, Sept. 30, 1986]

PART 455—PROGRAM INTEGRITY: MEDICAID

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AUTHORITY: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

SOURCE: 43 FR 45262, Sept. 29, 1978, unless otherwise noted.

§ 455.1 Basis and scope.

This part sets forth requirements for a State fraud detection and investigation program, and for disclosure of information on ownership and control.

(a) Under the authority of sections 1902(a)(4), 1903(i)(2), and 1909 of the Social Security Act, Subpart A provides State plan requirements for the identification, investigation, and referral of suspected fraud and abuse cases. In addition, the subpart requires that the State—

(1) Report fraud and abuse information to the Department; and

(2) Have a method to verify whether services reimbursed by Medicaid were actually furnished to recipients.

(b) Subpart B implements sections 1124, 1126, 1902(a)(36), 1903(i)(2), and 1903(n) of the Act. It requires that providers and fiscal agents must agree to disclose ownership and control information to the Medicaid State agency.

[51 FR 34787, Sept. 30, 1986]

§ 455.2 Definitions.

As used in this part unless the context indicates otherwise—

Abuse means provider practices that are inconsistent with sound fiscal, business, or medical practices, and result in an unnecessary cost to the Medicaid program, or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care. It also includes recipient practices that result in unnecessary cost to the Medicaid program.

Conviction or *Convicted* means that a judgment of conviction has been entered by a Federal, State, or local court, regardless of whether an appeal from that judgment is pending.

Exclusion means that items or services furnished by a specific provider who has defrauded or abused the Medicaid program will not be reimbursed under Medicaid.

Fraud means an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable Federal or State law.

Furnished refers to items and services provided directly by, or under the direct supervision of, or ordered by, a practitioner or other individual (either as an employee or in his or her own capacity), a provider, or other supplier of services. (For purposes of denial of reimbursement within this part, it does not refer to services ordered by one party but billed for and provided by or under the supervision of another.)

Practitioner means a physician or other individual licensed under State law to practice his or her profession.

Suspension means that items or services furnished by a specified provider who has been convicted of a program-related offense in a Federal, State, or local court will not be reimbursed under Medicaid.

[48 FR 3755, Jan. 27, 1983, as amended at 50 FR 37375, Sept. 13, 1985; 51 FR 34788, Sept. 30, 1986]

§ 455.3 Other applicable regulations.

Part 1002 of this title sets forth the following:

(a) State plan requirements for excluding providers for fraud and abuse, and suspending practitioners convicted of program-related crimes.

(b) The limitations on FFP for services furnished by excluded providers or suspended practitioners.

(c) The requirements and procedures for reinstatement after exclusion or suspension.

(d) Requirements for the establishment and operation of State Medicaid fraud control units and the rates of FFP for their fraud control activities.

[51 FR 34788, Sept. 30, 1986]

Subpart A—Medicaid Agency Fraud Detection and Investigation Program

§ 455.12 State plan requirement.

A State plan must meet the requirements of §§ 455.13 through 455.23.

[52 FR 48817, Dec. 28, 1987]

§ 455.13 Methods for identification, investigation, and referral.

The Medicaid agency must have—

(a) Methods and criteria for identifying suspected fraud cases;

(b) Methods for investigating these cases that—

(1) Do not infringe on the legal rights of persons involved; and

(2) Afford due process of law; and

(c) Procedures, developed in cooperation with State legal authorities, for referring suspected fraud cases to law enforcement officials.

[43 FR 45262, Sept. 29, 1978, as amended at 48 FR 3755, Jan. 27, 1983]

§ 455.14 Preliminary investigation.

If the agency receives a complaint of Medicaid fraud or abuse from any source or identifies any questionable practices, it must conduct a preliminary investigation to determine whether there is sufficient basis to warrant a full investigation.

[48 FR 3756, Jan. 27, 1983]

§ 455.15 Full investigation.

If the findings of a preliminary investigation give the agency reason to believe that an incident of fraud or abuse has occurred in the Medicaid program, the agency must take the following action, as appropriate:

(a) If a provider is suspected of fraud or abuse, the agency must—

(1) In States with a State Medicaid fraud control unit certified under Subpart C of Part 1002 of this title , refer the case to the unit under the terms of its agreement with the unit entered into under § 1002.309 of this title; or

(2) In States with no certified Medicaid fraud control unit, or in cases where no referral to the State Medicaid fraud control unit is required under paragraph (a)(1) of this section,

conduct a full investigation or refer the case to the appropriate law enforcement agency.

(b) If there is reason to believe that a recipient has defrauded the Medicaid program, the agency must refer the case to an appropriate law enforcement agency.

(c) If there is reason to believe that a recipient has abused the Medicaid program, the agency must conduct a full investigation of the abuse.

[48 FR 3756, Jan. 27, 1983, as amended at 51 FR 34788, Sept. 30, 1986]

§ 455.16 Resolution of full investigation.

A full investigation must continue until—

(a) Appropriate legal action is initiated;

(b) The case is closed or dropped because of insufficient evidence to support the allegations of fraud or abuse; or

(c) The matter is resolved between the agency and the provider or recipient. This resolution may include but is not limited to—

(1) Sending a warning letter to the provider or recipient, giving notice that continuation of the activity in question will result in further action;

(2) Suspending or terminating the provider from participation in the Medicaid program;

(3) Seeking recovery of payments made to the provider; or

(4) Imposing other sanctions provided under the State plan.

[43 FR 45262, Sept. 29, 1978, as amended at 48 FR 3756, Jan. 27, 1983]

§ 455.17 Reporting requirements.

The agency must report the following fraud or abuse information to the appropriate Department officials at intervals prescribed in instructions.

(a) The number of complaints of fraud and abuse made to the agency that warrant preliminary investigation.

(b) For each case of suspected provider fraud and abuse that warrants a full investigation—

(1) The provider's name and number;

(2) The source of the complaint;

(3) The type of provider;

(4) The nature of the complaint;

(5) The approximate range of dollars involved; and

(6) The legal and administrative disposition of the case, including actions taken by law enforcement officials to whom the case has been referred.

(Approved by the Office of Management and Budget under control number 0938-0076)

[43 FR 45262, Sept. 29, 1978, as amended at 48 FR 3756, Jan. 27, 1983]

§ 455.18 Provider's statements on claims forms.

(a) Except as provided in § 455.19, the agency must provide that all provider claims forms be imprinted in boldface type with the following statements, or with alternate wording that is approved by the Regional HCFA Administrator:

(1) "This is to certify that the foregoing information is true, accurate, and complete."

(2) "I understand that payment of this claim will be from Federal and State funds, and that any falsification, or concealment of a material fact, may be prosecuted under Federal and State laws."

(b) The statements may be printed above the claimant's signature or, if they are printed on the reverse of the form, a reference to the statements must appear immediately preceding the claimant's signature.

§ 455.19 Provider's statement on check.

As an alternative to the statements required in § 455.18, the agency may print the following wording above the claimant's endorsement on the reverse of checks or warrants payable to each provider: "I understand in endorsing or depositing this check that payment will be from Federal and State funds and that any falsification, or concealment of a material fact, may be prosecuted under Federal and State laws."

§ 455.20 Recipient verification procedure.

(a) The agency must have a method for verifying with recipients whether services billed by providers were received.

(b) In States receiving Federal matching funds for a mechanized claims processing and information retrieval system under Part 433, Subpart C, of this subchapter, the agency must provide prompt written notice as required by § 433.113 (e) and (f).

[48 FR 3756, Jan. 27, 1983]

§ 455.21 Cooperation with State Medicaid fraud control units.

In a State with a Medicaid fraud control unit established and certified under Subpart D of this part,

(a) The agency must—

(1) Refer all cases of suspected provider fraud to the unit;

(2) If the unit determines that it may be useful in carrying out the unit's responsibilities, promptly comply with a request from the unit for—

(i) Access to, and free copies of, any records or information kept by the agency or its contractors;

(ii) Computerized data stored by the agency or its contractors. These data must be supplied without charge and in the form requested by the unit; and

(iii) Access to any information kept by providers to which the agency is authorized access by section 1902(a)(27) of the Act and § 431.107 of this subchapter. In using this information, the unit must protect the privacy rights of recipients; and

(3) On referral from the unit, initiate any available administrative or judicial action to recover improper payments to a provider.

(b) The agency need not comply with specific requirements under this subpart that are the same as the responsibilities placed on the unit under Subpart D of this part.

§ 455.23 Withholding of payments in cases of fraud or willful misrepresentation.

(a) *Basis for withholding.* The State Medicaid agency may withhold Medicaid payments, in whole or in part, to a provider upon receipt of reliable evidence that the circumstances giving rise to the need for a withholding of payments involve fraud or willful misrepresentation under the Medicaid program. The State Medicaid agency may withhold payments without first notifying the provider of its intention to withhold such payments. A provider may request, and must be granted, administrative review where State law so requires.

(b) *Notice of withholding.* The State agency must send notice of its withholding of program payments within 5 days of taking such action. The notice must set forth the general allegations as to the nature of the withholding action, but need not disclose any specific information concerning its ongoing investigation. The notice must:

(1) State that payments are being withheld in accordance with this provision;

(2) State that the withholding is for a temporary period, as stated in paragraph (c) of this section, and cite the circumstances under which withholding will be terminated;

(3) Specify, when appropriate, to which type or types of Medicaid claims withholding is effective; and

(4) Inform the provider of the right to submit written evidence for consideration by the agency.

(c) *Duration of withholding.* All withholding of payment actions under this section will be temporary and will not continue after:

(1) The agency or the prosecuting authorities determine that there is insufficient evidence of fraud or willful misrepresentation by the provider; or

(2) Legal proceedings related to the provider's alleged fraud or willful misrepresentation are completed.

[52 FR 48817, Dec. 28, 1987]

Subpart B—Disclosure of Information by Providers and Fiscal Agents

SOURCE: 44 FR 41644, July 17, 1979, unless otherwise noted.

§ 455.100 Purpose.

This subpart implements sections 1124, 1126, 1902(a)(38), 1903(i)(2), and 1903(n) of the Social Security Act. It sets forth State plan requirements regarding—

(a) Disclosure by providers and fiscal agents of ownership and control information; and

(b) Disclosure of information on a provider's owners and other persons convicted of criminal offenses against Medicare, Medicaid, or the title XX services program.

The subpart also specifies conditions under which the Administrator will deny Federal financial participation for services furnished by providers or fiscal agents who fail to comply with the disclosure requirements.

§ 455.101 Definitions.

Agent means any person who has been delegated the authority to obligate or act on behalf of a provider.

Disclosing entity means a Medicaid provider (other than an individual practitioner or group of practitioners), or a fiscal agent.

Other disclosing entity means any other Medicaid disclosing entity and any entity that does not participate in Medicaid, but is required to disclose certain ownership and control information because of participation in any of the programs established under title V, XVIII, or XX of the Act. This includes:

(a) Any hospital, skilled nursing facility, home health agency, independent clinical laboratory, renal disease facility, rural health clinic, or health maintenance organization that participates in Medicare (title XVIII);

(b) Any Medicare intermediary or carrier; and

(c) Any entity (other than an individual practitioner or group of practitioners) that furnishes, or arranges for the furnishing of, health-related services for which it claims payment under any plan or program established under title V or title XX of the Act.

Fiscal agent means a contractor that processes or pays vendor claims on behalf of the Medicaid agency.

Group of practitioners means two or more health care practitioners who practice their profession at a common location (whether or not they share common facilities, common supporting staff, or common equipment).

Indirect ownership interest means an ownership interest in an entity that has an ownership interest in the disclosing entity. This term includes an ownership interest in any entity that has an indirect ownership interest in the disclosing entity.

Managing employee means a general manager, business manager, administrator, director, or other individual who exercises operational or managerial control over, or who directly or indirectly conducts the day-to-day operation of an institution, organization, or agency.

Ownership interest means the possession of equity in the capital, the stock, or the profits of the disclosing entity.

Person with an ownership or control interest means a person or corporation that—

(a) Has an ownership interest totaling 5 percent or more in a disclosing entity;

(b) Has an indirect ownership interest equal to 5 percent or more in a disclosing entity;

(c) Has a combination of direct and indirect ownership interests equal to 5 percent or more in a disclosing entity;

(d) Owns an interest of 5 percent or more in any mortgage, deed of trust, note, or other obligation secured by the disclosing entity if that interest equals at least 5 percent of the value of the property or assets of the disclosing entity;

(e) Is an officer or director of a disclosing entity that is organized as a corporation; or

(f) Is a partner in a disclosing entity that is organized as a partnership.

Significant business transaction means any business transaction or series of transactions that, during any one fiscal year, exceed the lesser of $25,000 and 5 percent of a provider's total operating expenses.

Subcontractor means—

(a) An individual, agency, or organization to which a disclosing entity has contracted or delegated some of its management functions or responsibilities of providing medical care to its patients; or

(b) An individual, agency, or organization with which a fiscal agent has entered into a contract, agreement, purchase order, or lease (or leases of real property) to obtain space, supplies, equipment, or services provided under the Medicaid agreeement.

Supplier means an individual, agency, or organization from which a provider purchases goods and services used in carrying out its responsibilities under Medicaid (e.g., a commercial laundry, a manufacturer of hospital beds, or a pharmaceutical firm).

Wholly owned supplier means a supplier whose total ownership interest is held by a provider or by a person, persons, or other entity with an ownership or control interest in a provider.

[44 FR 41644, July 17, 1979, as amended at 51 FR 34788, Sept. 30, 1986]

§ 455.102 Determination of ownership or control percentages.

(a) *Indirect ownership interest.* The amount of indirect ownership interest is determined by multiplying the percentages of ownership in each entity. For example, if A owns 10 percent of the stock in a corporation which owns 80 percent of the stock of the disclosing entity, A's interest equates to an 8 percent indirect ownership interest in the disclosing entity and must be reported. Conversely, if B owns 80 percent of the stock of a corporation which owns 5 percent of the stock of the disclosing entity, B's interest equates to a 4 percent indirect ownership interest in the disclosing entity and need not be reported.

(b) *Person with an ownership or control interest.* In order to determine percentage of ownership, mortgage, deed of trust, note, or other obligation, the percentage of interest owned in the obligation is multiplied by the percentage of the disclosing entity's assets used to secure the obligation. For example, if A owns 10 percent of a note secured by 60 percent of the provider's assets, A's interest in the provider's assets equates to 6 percent and must be reported. Conversely, if B owns 40 percent of a note secured by 10 percent of the provider's assets, B's interest in the provider's assets equates to 4 percent and need not be reported.

§ 455.103 State plan requirement.

A State plan must provide that the requirements of §§ 455.104 through 455.106 are met.

§ 455.104 Disclosure by providers and fiscal agents: Information on ownership and control.

(a) *Information that must be disclosed.* The Medicaid agency must require each disclosing entity to disclose the following information in accordance with paragraph (b) of this section:

(1) The name and address of each person with an ownership or control interest in the disclosing entity or in any subcontractor in which the disclosing entity has direct or indirect ownership of 5 percent or more;

(2) Whether any of the persons named, in compliance with paragraph (a)(1) of this section, is related to another as spouse, parent, child, or sibling.

(3) The name of any other disclosing entity in which a person with an ownership or control interest in the disclosing entity also has an ownership or control interest. This requirement applies to the extent that the disclosing entity can obtain this information by requesting it in writing from the person. The disclosing entity must—

(i) Keep copies of all these requests and the responses to them;

(ii) Make them available to the Secretary or the Medicaid agency upon request; and

(iii) Advise the Medicaid agency when there is no response to a request.

(b) *Time and manner of disclosure.* (1) Any disclosing entity that is subject to periodic survey and certification of its compliance with Medicaid standards must supply the information specified in paragraph (a) of this section to the State survey agency at the time it is surveyed. The survey agency must promptly furnish the information to the Secretary and the Medicaid agency.

(2) Any disclosing entity that is not subject to periodic survey and certification and has not supplied the information specified in paragraph (a) of this section to the Secretary within the prior 12-month period, must submit the information to the Medicaid agency before entering into a contract or agreement to participate in the program. The Medicaid agency must promptly furnish the information to the Secretary.

(3) Updated information must be furnished to the Secretary or the State survey or Medicaid agency at intervals between recertification or contract renewals, within 35 days of a written request.

(c) *Provider agreements and fiscal agent contracts.* A Medicaid agency shall not approve a provider agreement or a contract with a fiscal agent, and must terminate an existing agreement or contract, if the provider or fiscal agent fails to disclose ownership or control information as required by this section.

(d) *Denial of Federal financial participation (FFP).* FFP is not available in payments made to a provider or fiscal agent that fails to disclose ownership or control information as required by this section.

§ 455.105 Disclosure by providers: Information related to business transactions.

(a) *Provider agreements.* A Medicaid agency must enter into an agreement with each provider under which the provider agrees to furnish to it or to the Secretary on request, information related to business transactions in accordance with paragraph (b) of this section.

(b) *Information that must be submitted.* A provider must submit, within 35 days of the date on a request by the Secretary or the Medicaid agency, full and complete information about—

(1) The ownership of any subcontractor with whom the provider has had business transactions totaling more than $25,000 during the 12-month period ending on the date of the request; and

(2) Any significant business transactions between the provider and any wholly owned supplier, or between the provider and any subcontractor, during the 5-year period ending on the date of the request.

(c) *Denial of Federal financial participation (FFP).* (1) FFP is not available in expenditures for services furnished by providers who fail to comply with a request made by the Secretary or the Medicaid agency under paragraph (b) of this section or under § 420.205 of this chapter (Medicare requirements for disclosure).

(2) FFP will be denied in expenditures for services furnished during the period beginning on the day following the date the information was due to the Secretary or the Medicaid agency and ending on the day before the date on which the information was supplied.

§ 455.106 Disclosure by providers: Information on persons convicted of crimes.

(a) *Information that must be disclosed.* Before the Medicaid agency enters into or renews a provider agreement, or at any time upon written request by the Medicaid agency, the provider must disclose to the Medicaid agency the identity of any person who:

(1) Has ownership or control interest in the provider, or is an agent or managing employee of the provider; and

(2) Has been convicted of a criminal offense related to that person's involvement in any program under Medicare, Medicaid, or the title XX services program since the inception of those programs.

(b) *Notification to Inspector General.* (1) The Medicaid agency must notify the Inspector General of the Department of any disclosures made under paragraph (a) of this section within 20 working days from the date it receives the information.

(2) The agency must also promptly notify the Inspector General of the Department of any action it takes on the provider's application for participation in the program.

(c) *Denial or termination of provider participation.* (1) The Medicaid agency may refuse to enter into or renew an agreement with a provider if any person who has an ownership or control interest in the provider, or who is an agent or managing employee of the provider, has been convicted of a criminal offense related to that person's involvement in any program established under Medicare, Medicaid or the title XX Services Program.

(2) The Medicaid agency may refuse to enter into or may terminate a provider agreement if it determines that the provider did not fully and accurately make any disclosure required under paragraph (a) of this section.

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AUTHORITY: Sec. 1102 of the Social Security Act (42 U.S.C. 1302), unless otherwise noted.

SOURCE: 43 FR 45266, Sept. 29, 1978, unless otherwise noted.

Subpart A—General Provisions

§ 456.1 Basis and purpose of part.

(a) This part prescribes requirements concerning control of the utilization of Medicaid services including—

(1) A statewide program of control of the utilization of all Medicaid services; and

(2) Specific requirements for the control of the utilization of Medicaid services in institutions.

(b) The requirements in this part are based on the following sections of the Act. Table 1 shows the relationship between these sections of the Act and the requirements in this part.

(1) *Methods and procedures to safeguard against unnecessary utilization of care and services.* Section 1902(a)(30) requires that the State plan provide methods and procedures to safeguard against unnecessary utilization of care and services.

(2) *Penalty for failure to have an effective program to control utilization of institutional services.* Section 1903(g)(1) provides for a reduction in the amount of Federal Medicaid funds paid to a State for long-stay inpatient services if the State does not make a showing satisfactory to the Secretary that it has an effective program of control over utilization of those services. This penalty provision applies to inpatient services in hospitals, mental hospitals, skilled nursing facilities (SNF's), and intermediate care facilities (ICF's). Specific requirements are:

(i) Under section 1903(g)(1)(A), a physician must certify at admission, and a physician (or physician assistant or nurse practitioner under the supervision of a physician) must periodically recertify, the individual's need for inpatient care.

(ii) Under section 1903(g)(1)(B), services must be furnished under a plan established and periodically evaluated by a physician.

(iii) Under section 1903(g)(1)(C), the State must have in effect a continuous program of review of utilization of care and services under section 1902(a)(30) whereby each admission is reviewed or screened in accordance with criteria established by medical and other professional personnel.

(iv) Under section 1903(g)(1)(D), the State must have an effective program under sections 1902(a) (26) and (31) of review of care in skilled nursing and intermediate care facilities and mental hospitals. This must include evaluation at least annually of the professional management of each case.

(3) *Medical review in skilled nursing facilities and mental hospitals.* Section 1902(a)(26)(A) requires that the plan provide for a program of medical review that includes a medical evaluation of each individual's need for care in a SNF or mental hospital, a plan of care, and, where applicable, a plan of rehabilitation.

(4) *Independent professional review in intermediate care facilities.* Section 1902(a)(31)(A) requires that the plan provide for a program of independent professional review that includes a medical evaluation of each individual's need for intermediate care and a written plan of service.

(5) *Inspection of care and services in institutions.* Sections 1902(a)(26) (B) and (C) and 1902(a)(31) (B) and (C) require that the plan provide for periodic inspections and reports, by a team of professional persons, of the care being provided to each recipient in SNF's, institutions for mental diseases (IMD's), and ICF's participating in Medicaid.

(6) *Denial of FFP for failure to have specified utilization review procedures.* Section 1903(i)(4) provides that FFP is not available in a State's expenditures for hospital, mental hospital, or SNF services unless the institution has in effect a utilization review plan that meets Medicare requirements. However, the Secretary may waive this requirement if the Medicaid agency demonstrates to his satisfaction that it has utilization review procedures superior in effectiveness to the Medicare procedures.

(7) *State health agency guidance on quality and appropriateness of care and services.* Section 1902(a)(33)(A) requires that the plan provide that the State health or other appropriate medical agency establish a plan for review, by professional health personnel, of the appropriateness and quality of Medicaid services to provide guidance to the Medicaid agency and the State licensing agency in administering the Medicaid program.

TABLE 1

[This table relates the regulations in this part to the sections of the Act on which they are based.]

Subpart A—General	1902(a)(30) 1902(a)(33)(A)
Subpart B—Utilization Control: All Medicaid Services.	1902(a)(30)
Subpart C—Utilization Control: Hospitals	
Certification of need for care	1903(g)(1)(A)
Plan of care	1903(g)(1)(B)
Utilization review plan (including admission review).	1902(a)(30) 1903(g)(1)(C) 1903(i)(4)
Subpart D—Utilization Control: Mental Hospitals	
Certification of need for care	1903(g)(1)(A)
Medical evaluation and admission review.	1902(a)(26)(A) 1903(g)(1)(C)
Plan of care	1902(a)(26)(A) 1903(g)(1)(B)
Admission and plan of care requirements for individuals under 21.	1902(a)(26)(A) 1903(g)(1) (B), (C)
Utilization review plan	1902(a)(30) 1903(g)(1)(C) 1903(i)(4)
Subpart E—Utilization Control: Skilled Nursing Facilities	
Certification of need for care	1903(g)(1)(A)
Medical evaluation and admission review.	1902(a)(26)(A) 1903(g)(1)(C)
Plan of care	1902(a)(26)(A) 1903(g)(1)(B)
Utilization review plan	1902(a)(30) 1903(g)(1)(C) 1903(i)(4)
Discharge plan	1902(a)(30)
Subpart F—Utilization Control: Intermediate Care Facilities	
Certification of need for care	1903(g)(1)(A)
Medical evaluation and admission review	1902(a)(31)(A) 1903(g)(1)(C)
Plan of care	1902(a)(31)(A) 1903(g)(1)(B)
Utilization review plan	1902(a)(30) 1903(g)(1)(C) 1903(i)(4)
Subpart G—Inpatient Psychiatric Services for Individuals Under Age 21: Admission and Plan of Care Requirements.	1905 (a)(16) and (h)
Subpart H—Utilization Review Plans: FFP, Waivers, and Variances for Hospitals, Mental Hospitals and Skilled Nursing Facilities.	1902(a)(30) 1903(i)(4)
Subpart I—Inspections of Care in Skilled Nursing and Intermediate Care Facilities and Institutions for Mental Diseases.	1902(a)(26) (B), (C), (31) (B), (C) 1903(g)(1)(D)

[43 FR 45266, Sept. 29, 1978, as amended at 46 FR 48561, Oct. 1, 1981]

§ 456.2 State plan requirements.

(a) A State plan must provide that the requirements of this part are met.

(b) These requirements may be met by the agency by:

(1) Assuming direct responsibility for assuring that the requirements of this part are met; or

(2) Deeming of medical and utilization review requirements if the agency contracts with a PRO to perform that review, which in the case of inpatient acute care review will also serve as the initial determination for PRO medical necessity and appropriateness review for patients who are dually entitled to benefits under Medicare and Medicaid.

(c) In accordance with § 431.15 of this subchapter, FFP will be available for expenses incurred in meeting the requirements of this part.

[46 FR 48566, Oct. 1, 1981, as amended at 50 FR 15327, Apr. 17, 1985; 51 FR 43198, Dec. 1, 1986]

§ 456.3 Statewide surveillance and utilization control program.

The Medicaid agency must implement a statewide surveillance and utilization control program that—

(a) Safeguards against unnecessary or inappropriate use of Medicaid services and against excess payments;

(b) Assesses the quality of those services;

(c) Provides for the control of the utilization of all services provided under the plan in accordance with Subpart B of this part; and

(d) Provides for the control of the utilization of inpatient services in accordance with Subparts C through I of this part.

§ 456.4 Responsibility for monitoring the utilization control program.

(a) The agency must—

(1) Monitor the statewide utilization control program;

(2) Take all necessary corrective action to ensure the effectiveness of the program;

(3) Establish methods and procedures to implement this section;

(4) Keep copies of these methods and procedures on file; and

(5) Give copies of these methods and procedures to all staff involved in carrying out the utilization control program.

§ 456.5 Evaluation criteria.

The agency must establish and use written criteria for evaluating the appropriateness and quality of Medicaid services. This section does not apply to services in hospitals, mental hospitals, and SNFs. For these facilities, see the following sections: §§ 456.122 and 456.132 of Subpart C; § 456.232 of Subpart D; and § 456.332 of Subpart E.

§ 456.6 Review by State medical agency of appropriateness and quality of services.

(a) The Medicaid agency must have an agreement with the State health agency or other appropriate State medical agency, under which the health or medical agency is responsible for establishing a plan for the review by professional health personnel of the appropriateness and quality of Medicaid services.

(b) The purpose of this review plan is to provide guidance to the Medicaid agency in the administration of the State plan and, where applicable, to the State licensing agency described in § 431.610.

Subpart B—Utilization Control: All Medicaid Services

§ 456.21 Scope.

This subpart prescribes utilization control requirements applicable to all services provided under a State plan.

§ 456.22 Sample basis evaluation of services.

To promote the most effective and appropriate use of available services and facilities the Medicaid agency must have procedures for the on-going evaluation, on a sample basis, of the need for and the quality and timeliness of Medicaid services.

§ 456.23 Post-payment review process.

The agency must have a post-payment review process that—

(a) Allows State personnel to develop and review—

(1) Recipient utilization profiles;

(2) Provider service profiles; and

(3) Exceptions criteria; and

(b) Identifies exceptions so that the agency can correct misutilization practices of recipients and providers.

Subpart C—Utilization Control: Hospitals

§ 456.50 Scope.

This subpart prescribes requirements for control of utilization of inpatient hospital services, including requirements concerning—

(a) Certification of need for care;

(b) Plan of care; and

(c) Utilization review plans.

§ 456.51 Definitions.

As used in this subpart:

Inpatient hospital services—

(a) Include—

(1) Services provided in an institution other than an institution for mental disease, as defined in § 440.10;

(2) [Reserved]

(3) Services provided in specialty hospitals and

(b) Exclude services provided in mental hospitals. Utilization control requirements for mental hospitals appear in Subpart D.

Medical care appraisal norms or *norms* means numerical or statistical measures of usually observed performance.

Medical care criteria or *criteria* means predetermined elements against which aspects of the quality of a medical service may be compared. These criteria are developed by health professionals relying on their expertise and the professional health care literature.

[43 FR 45266, Sept. 29, 1978, as amended at 51 FR 22041, June 17, 1986]

CERTIFICATION OF NEED FOR CARE

§ 456.60 Certification and recertification of need for inpatient care.

(a) *Certification.* (1) A physician must certify for each applicant or recipient that inpatient services in a hospital are or were needed.

(2) The certification must be made at the time of admission or, if an individual applies for assistance while in a hospital, before the Medicaid agency authorizes payment.

(b) *Recertification.* (1) A physician, or physician assistant or nurse practitioner (as defined in § 491.2 of this chapter) acting within the scope of practice as defined by State law and under the supervision of a physician, must recertify for each applicant or recipient that inpatient services in a hospital are needed.

(2) Recertifications must be made at least every 60 days after certification.

[46 FR 48561, Oct. 1, 1981]

PLAN OF CARE

§ 456.80 Individual written plan of care.

(a) Before admission to a hospital or before authorization for payment, a physician and other personnel involved in the care of the individual must establish a written plan of care for each applicant or recipient.

(b) The plan of care must include—

(1) Diagnoses, symptoms, complaints, and complications indicating the need for admission;

(2) A description of the functional level of the individual;

(3) Any orders for—

(i) Medications;

(ii) Treatments;

(iii) Restorative and rehabilitative services;

(iv) Activities;

(v) Social services;

(vi) Diet;

(4) Plans for continuing care, as appropriate; and

(5) Plans for discharge, as appropriate.

(c) Orders and activities must be developed in accordance with physician's instructions.

(d) Orders and activities must be reviewed and revised as appropriate by all personnel involved in the care of an individual.

(e) A physician and other personnel involved in the recipient's case must review each plan of care at least every 60 days.

UTILIZATION REVIEW (UR) PLAN: GENERAL REQUIREMENT

§ 456.100 Scope.

Sections 456.101 through 456.145 of this subpart prescribe requirements for a written utilization review (UR) plan for each hospital providing Medicaid services. Sections 456.105 and 456.106 prescribe administrative requirements; §§ 456.111 through 456.113 prescribe informational requirements; §§ 456.121 through 456.129 prescribe requirements for admission review; §§ 456.131 through 456.137 prescribe requirements for continued stay review; and §§ 456.141 through 456.145 prescribe requirements for medical care evaluation studies.

§ 456.101 UR plan required for inpatient hospital services.

(a) A State plan must provide that each hospital furnishing inpatient services under the plan has in effect a written UR plan that provides for review of each recipient's need for the services that the hospital furnishes him.

(b) Each written hospital UR plan must meet the requirements under §§ 456.101 through 456.145.

UR PLAN: ADMINISTRATIVE REQUIREMENTS

§ 456.105 UR committee required.

The UR plan must—

(a) Provide for a committee to perform UR required under this subpart;

(b) Describe the organization, composition, and functions of this committee; and

(c) Specify the frequency of meetings of the committee.

§ 456.106 Organization and composition of UR committee; disqualification from UR committee membership.

(a) For the purpose of this subpart, "UR committee" includes any group organized under paragraphs (b) and (c) of this section.

(b) The UR committee must be composed of two or more physicians, and assisted by other professional personnel.

(c) The UR committee must be constituted as—

(1) A committee of the hospital staff;

(2) A group outside the hospital staff, established by the local medical or osteopathic society and at least some of the hospitals and SNFs in the locality;

(3) A group capable of performing utilization review, established and or-

ganized in a manner approved by the Secretary.

(d) The UR committee may not include any individual who—

(1) Is directly responsible for the care of the patient whose care is being reviewed; or

(2) Has a financial interest in any hospital.

UR PLAN: INFORMATIONAL REQUIREMENTS

§ 456.111 Recipient information required for UR.

The UR plan must provide that each recipient's record includes information needed for the UR committee to perform UR required under this subpart. This information must include, at least, the following:

(a) Identification of the recipient.

(b) The name of the recipient's physician.

(c) Date of admission, and dates of application for and authorization of Medicaid benefits if application is made after admission.

(d) The plan of care required under § 456.70.

(e) Initial and subsequent continued stay review dates described under §§ 456.128 and 456.133.

(f) Date of operating room reservation, if applicable.

(g) Justification of emergency admission, if applicable.

(h) Reasons and plan for continued stay, if the attending physician believes continued stay is necessary.

(i) Other supporting material that the committee believes appropriate to be included in the record.

§ 456.112 Records and reports.

The UR plan must describe—

(a) The types of records that are kept by the committee; and

(b) The type and frequency of committee reports and arrangements for their distribution to appropriate individuals.

§ 456.113 Confidentiality.

The UR plan must provide that the identities of individual recipients in all UR records and reports are kept confidential.

UR PLAN: REVIEW OF NEED FOR ADMISSION [1]

§ 456.121 Admission review required.

The UR plan must provide for a review of each recipient's admission to the hospital to decide whether it is needed, in accordance with the requirements of §§ 456.122 through 456.129.

§ 456.122 Evaluation criteria for admission review.

The UR plan must provide that—

(a) The committee develops written medical care criteria to assess the need for admission; and

(b) The committee develops more extensive written criteria for cases that its experience shows are—

(1) Associated with high costs;

(2) Associated with the frequent furnishing of excessive services; or

(3) Attended by physicians whose patterns of care are frequently found to be questionable.

§ 456.123 Admission review process.

The UR plan must provide that—

(a) Admission review is conducted by—

(1) The UR committee;

(2) A subgroup of the UR committee; or

(3) A designee of the UR committee;

(b) The committee, subgroup, or designee evaluates the admission against the criteria developed under § 456.122 and applies close professional scrutiny to cases selected under § 456.129(b);

(c) If the committee, subgroup, or designee finds that the admission is needed, the committee assigns an initial continued stay review date in accordance with § 456.128;

(d) If the committee, subgroup, or designee finds that the admission does not meet the criteria, the committee or a subgroup that includes at least one physician reviews the case to decide the need for admission;

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[1] The Department was enjoined in 1975 in the case of American Medical Assn. et al. v. Weinberger, 395 F. Supp. 515 (N.D. Ill., 1975), aff'd., 522 F2d 921 (7th cir., 1975) from implementing the admission review requirements contained in §§ 456.121-456.127. This case was dismissed on the condition that these requirements be revised. They are presently being revised, and will not be in force until that revision is completed.

(e) If the committee or subgroup making the review under paragraph (d) of this section finds that the admission is not needed, it notifies the recipient's attending physician and gives him an opportunity to present his views before it makes a final decision on the need for the continued stay;

(f) If the attending physician does not present additional information or clarification of the need for the admission, the decision of the committee or subgroup is final; and

(g) If the attending physician presents additional information or clarification, at least two physician members of the committee review the need for the admission. If they find that the admission is not needed, their decision if final.

§ 456.124 Notification of adverse decision.

The UR plan must provide that written notice of any adverse final decision on the need for admission under § 456.123 (e) through (g) is sent to—

(a) The hospital administrator;

(b) The attending physician;

(c) The Medicaid agency;

(d) The recipient; and

(e) If possible, the next of kin or sponsor.

§ 456.125 Time limits for admission review.

Except as required under § 456.127, the UR plan must provide that review of each recipient's admission to the hospital is conducted—

(a) Within one working day after admission, for an individual who is receiving Medicaid at that time; or

(b) Within one working day after the hospital is notified of the application for Medicaid, for an individual who applies while in the hospital.

§ 456.126 Time limits for final decision and notification of adverse decision.

Except as required under § 456.127, the UR plan must provide that the committee makes a final decision on a recipient's need for admission and gives notice of an adverse final decision—

(a) Within two working days after admission, for an individual who is receiving Medicaid at that time; or

(b) Within two working days after the hospital is notified of the application for Medicaid, for an individual who applies while in the hospital.

§ 456.127 Pre-admission review.

The UR plan must provide for review and final decision prior to admission for certain providers or categories of admissions that the UR committee designates under § 456.142(b)(4)(iii) to receive pre-admission review.

§ 456.128 Initial continued stay review date.

The UR plan must provide that—

(a) When a recipient is admitted to the hospital under the admission review requirements of this subpart, the committee assigns a specified date by which the need for his continued stay will be reviewed;

(b) The committee bases its assignment of the initial continued stay review date on—

(1) The methods and criteria required to be described under § 456.129;

(2) The individual's condition; and

(3) The individual's projected discharge date;

(c)(1) The committee uses any available appropriate regional medical care appraisal norms, such as those developed by abstracting services or third party payors, to assign the initial continued stay review date;

(2) These regional norms are based on current and statistically valid data on duration of stay in hospitals for patients whose characteristics, such as age and diagnosis, are similar to those of the individual whose case is being reviewed;

(3) If the committee uses norms to assign the initial continued stay review date, the number of days between the individual's admission and the initial continued stay review date is no greater than the number of days reflected in the 50th percentile of the norms. However, the committee may assign a later review date if it documents that the later date is more appropriate; and

(d) The committee ensures that the initial continued stay review date is recorded in the individual's record.

§ 456.129 Description of methods and criteria: Initial continued stay review date; close professional scrutiny; length of stay modification.

The UR plan must describe—

(a) The methods and criteria, including norms if used, that the committee uses to assign the initial continued stay review date under § 456.128.

(b) The methods that the committee uses to select categories of admission to receive close professional scrutiny under § 456.123(b); and

(c) The methods that the committee uses to modify an approved length of stay when the recipient's condition or treatment schedule changes.

UR PLAN: REVIEW OF NEED FOR CONTINUED STAY

§ 456.131 Continued stay review required.

The UR plan must provide for a review of each recipient's continued stay in the hospital to decide whether it is needed, in accordance with the requirements of §§ 456.132 through 456.137.

§ 456.132 Evaluation criteria for continued stay.

The UR plan must provide that—

(a) The committee develops written medical care criteria to assess the need for continued stay.

(b) The committee develops more extensive written criteria for cases that its experience shows are—

(1) Associated with high costs;

(2) Associated with the frequent furnishing of excessive services; or

(3) Attended by physicians whose patterns of care are frequently found to be questionable.

§ 456.133 Subsequent continued stay review dates.

The UR plan must provide that—

(a) The committee assigns subsequent continued stay review dates in accordance with §§ 456.128 and 456.134(a);

(b) The committee assigns a subsequent review date each time it decides under § 456.135 that the continued stay is needed; and

(c) The committee ensures that each continued stay review date it assigns is recorded in the recipient's record.

§ 456.134 Description of methods and criteria: Subsequent continued stay review dates; length of stay modification.

The UR plan must describe—

(a) The methods and criteria, including norms if used, that the committee uses to assign subsequent continued stay review dates under § 456.133; and

(b) The methods that the committee uses to modify an approved length of stay when the recipient's condition or treatment schedule changes.

§ 456.135 Continued stay review process.

The UR plan must provide that—

(a) Review of continued stay cases is conducted by—

(1) The UR committee;

(2) A subgroup of the UR committee; or

(3) A designee of the UR committee;

(b) The committee, subgroup or designee reviews a recipient's continued stay on or before the expiration of each assigned continued stay review date;

(c) For each continued stay of a recipient in the hospital, the committee, subgroup or designee reviews and evaluates the documentation described under § 456.111 against the criteria developed under § 456.132 and applies close professional scrutiny to cases selected under § 456.129(b);

(d) If the committee, subgroup, or designee finds that a recipient's continued stay in the hospital is needed, the committee assigns a new continued stay review date in accordance with § 456.133;

(e) If the committee, subgroup, or designee finds that a continued stay case does not meet the criteria, the committee or a subgroup that includes at least one physician reviews the case to decide the need for continued stay;

(f) If the committee or subgroup making the review under paragraph (e) of this section finds that a continued stay is not needed, it notifies the recipient's attending physician and gives him an opportunity to present his reviews before it makes a final decision on the need for the continued stay;

(g) If the attending physician does not present additional information or clarification of the need for the continued stay, the decision of the committee or subgroup is final; and

(h) If the attending physician presents additional information or clarification, at least two physician members of the committee review the need for the continued stay. If they find that the recipient no longer needs inpatient hospital services, their decision is final.

§ 456.136 Notification of adverse decision.

The UR plan must provide that written notice of any adverse final decision on the need for continued stay under § 456.135 (f) through (h) is sent to—

(a) The hospital administrator;

(b) The attending physician;

(c) The Medicaid agency;

(d) The recipient; and

(e) If possible, the next of kin or sponsor.

§ 456.137 Time limits for final decision and notification of adverse decision.

The UR plan must provide that—

(a) The committee makes a final decision on a recipient's need for continued stay and gives notice under § 456.136 of an adverse final decision within 2 working days after the assigned continued stay review dates, except as required under paragraph (b) of this section.

(b) If the committee makes an adverse final decision on a recipient's need for continued stay before the assigned review date, the committee gives notice under § 456.136 within 2 working days after the date of the final decision.

UR PLAN: MEDICAL CARE EVALUATION STUDIES

§ 456.141 Purpose and general description.

(a) The purpose of medical care evaluation studies is to promote the most effective and efficient use of available health facilities and services consistent with patient needs and professionally recognized standards of health care.

(b) Medical care evaluation studies—

(1) Emphasize identification and analysis of patterns of patient care; and

(2) Suggest appropriate changes needed to maintain consistently high quality patient care and effective and efficient use of services.

§ 456.142 UR plan requirements for medical care evaluation studies.

(a) The UR plan must describe the methods that the committee uses to select and conduct medical care evaluation studies under paragraph (b)(1) of this section.

(b) The UR plan must provide that the UR committee—

(1) Determines the methods to be used in selecting and conducting medical care evaluation studies in the hospital;

(2) Documents for each study—

(i) Its results; and

(ii) How the results have been used to make changes to improve the quality of care and promote more effective and efficient use of facilities and services;

(3) Analyzes its findings for each study; and

(4) Takes action as needed to—

(i) Correct or investigate further any deficiencies or problems in the review process for admissions or continued stay cases;

(ii) Recommend more effective and efficient hospital care procedures; or

(iii) Designate certain providers or categories of admissions for review prior to admission.

§ 456.143 Content of medical care evaluation studies.

Each medical care evaluation study must—

(a) Identify and analyze medical or administrative factors related to the hospital's patient care;

(b) Include analysis of at least the following:

(1) Admissions;

(2) Durations of stay;

(3) Ancillary services furnished, including drugs and biologicals;

(4) Professional services performed in the hospital; and

(c) If indicated, contain recommendations for changes beneficial to patients, staff, the hospital, and the community.

§ 456.144 Data sources for studies.

Data that the committee uses to perform studies must be obtained from one or more of the following sources:

(a) Medical records or other appropriate hospital data;

(b) External organizations that compile statistics, design profiles, and produce other comparative data;

(c) Cooperative endeavors with—

(1) PROs;

(2) Fiscal agents;

(3) Other service providers; or

(4) Other appropriate agencies.

[43 FR 45266, Sept. 29, 1978, as amended at 51 FR 43198, Dec. 1, 1986]

§ 456.145 Number of studies required to be performed.

The hospital must, at least, have one study in progress at any time and complete one study each calendar year.

Subpart D—Utilization Control: Mental Hospitals

§ 456.150 Scope.

This subpart prescribes requirements for control of utilization of inpatient services in mental hospitals, including requirements concerning—

(a) Certification of need for care;

(b) Medical evaluation and admission review;

(c) Plan of care; and

(d) Utilization review plans.

§ 456.151 Definitions.

As used in this subpart:

Medical care appraisal norms or *norms* means numerical or statistical measures of usually observed performance.

Medical care criteria or *criteria* means predetermined elements against which aspects of the quality of a medical service may be compared. These criteria are developed by health professionals relying on their expertise and the professional health care literature.

CERTIFICATION OF NEED FOR CARE

§ 456.160 Certification and recertification of need for inpatient care.

(a) *Certification.* (1) A physician must certify for each applicant or recipient that inpatient services in a mental hospital are or were needed.

(2) The certification must be made at the time of admission or, if an individual applies for assistance while in a mental hospital, before the Medicaid agency authorizes payment.

(b) *Recertification.* (1) A physician, or physician assistant or nurse practitioner (as defined in § 491.2 of this chapter) acting within the scope of practice as defined by State law and under the supervision of a physician, must recertify for each applicant or recipient that inpatient services in a mental hospital are needed.

(2) Recertification must be made at least every 60 days after certification.

[46 FR 48561, Oct. 1, 1981]

MEDICAL, PSYCHIATRIC, AND SOCIAL EVALUATIONS AND ADMISSION REVIEW

§ 456.170 Medical, psychiatric, and social evaluations.

(a) Before admission to a mental hospital or before authorization for payment, the attending physician or staff physician must make a medical evaluation of each applicant's or recipient's need for care in the hospital; and appropriate professional personnel must make a psychiatric and social evaluation.

(b) Each medical evaluation must include—

(1) Diagnoses;

(2) Summary of present medical findings;

(3) Medical history;

(4) Mental and physical functional capacity;

(5) Prognoses; and

(6) A recommendation by a physician concerning—

(i) Admission to the mental hospital; or

(ii) Continued care in the mental hospital for individuals who apply for Medicaid while in the mental hospital.

§ 456.171 Medicaid agency review of need for admission.

Medical and other professional personnel of the Medicaid agency or its designees must evaluate each applicant's or recipient's need for admission by reviewing and assessing the evaluations required by § 456.170.

PLAN OF CARE

§ 456.180 Individual written plan of care.

(a) Before admission to a mental hospital or before authorization for payment, the attending physician or staff physician must establish a written plan of care for each applicant or recipient.

(b) The plan of care must include—

(1) Diagnoses, symptoms, complaints, and complications indicating the need for admission;

(2) A description of the functional level of the individual;

(3) Objectives;

(4) Any orders for—

(i) Medications;

(ii) Treatments;

(iii) Restorative and rehabilitative services;

(iv) Activities;

(v) Therapies;

(vi) Social services;

(vii) Diet; and

(viii) Special procedures recommended for the health and safety of the patient;

(5) Plans for continuing care, including review and modification to the plan of care; and

(6) Plans for discharge.

(c) The attending or staff physician and other personnel involved in the recipient's care must review each plan of care at least every 90 days.

§ 456.181 Reports of evaluations and plans of care.

A written report of each evaluation and plan of care must be entered in the applicant's or recipient's record—

(a) At the time of admission; or

(b) If the individual is already in the facility, immediately upon completion of the evaluation or plan.

UTILIZATION REVIEW (UR) PLAN: GENERAL REQUIREMENTS

§ 456.200 Scope.

Sections 456.201 through 456.245 of this subpart prescribe requirements for a written utilization review (UR) plan for each mental hospital providing Medicaid services. Sections 456.205 and 456.206 prescribe administrative requirements; §§ 456.211 through 456.213 prescribe informational requirements; §§ 456.231 through 456.238 prescribe requirements for continued stay review; and §§ 456.241 through 456.245 prescribe requirements for medical care evaluation studies.

§ 456.201 UR plan required for inpatient mental hospital services.

(a) The State plan must provide that each mental hospital furnishing inpatient services under the plan has in effect a written UR plan that provides for review of each recipient's need for the services that the mental hospital furnishes him.

(b) Each written mental hospital UR plan must meet the requirements under §§ 456.201 through 456.245.

UR PLAN: ADMINISTRATIVE REQUIREMENTS

§ 456.205 UR committee required.

The UR plan must—

(a) Provide for a committee to perform UR required under this subpart;

(b) Describe the organization, composition, and functions of this committee; and

(c) Specify the frequency of meetings of the committee.

§ 456.206 Organization and composition of UR committee; disqualification from UR committee membership.

(a) For the purpose of this subpart, "UR committee" includes any group organized under paragraphs (b) and (c) of this section.

(b) The UR committee must be composed of two or more physicians, one of whom is knowledgeable in the diagnosis and treatment of mental diseases, and assisted by other professional personnel.

(c) The UR committee must be constituted as—

(1) A committee of the mental hospital staff;

(2) A group outside the mental hospital staff, established by the local medical or osteopathic society and at least some of the hospitals and SNFs in the locality; or

(3) A group capable of performing utilization review, established and organized in a manner approved by the Secretary.

(d) The UR committee may not include any individual who—

(1) Is directly responsible for the care of patients whose care is being reviewed; or

(2) Has a financial interest in any mental hospital.

UR PLAN: INFORMATIONAL REQUIREMENTS

§ 456.211 Recipient information required for UR.

The UR plan must provide that each recipient's record includes information needed to perform UR required under this subpart. This information must include, at least, the following:

(a) Identification of the recipient.

(b) The name of the recipient's physician.

(c) Date of admission, and dates of application for and authorization of Medicaid benefits if application is made after admission.

(d) The plan of care required under § 456.172.

(e) Initial and subsequent continued stay review dates described under §§ 456.233 and 456.234.

(f) Reasons and plan for continued stay, if the attending physician believes continued stay is necessary.

(g) Other supporting material that the committee believes appropriate to be included in the record.

§ 456.212 Records and reports.

The UR plan must describe—

(a) The types of records that are kept by the committee; and

(b) The type and frequency of committee reports and arrangements for their distribution to appropriate individuals.

§ 456.213 Confidentiality.

The UR plan must provide that the identities of individual recipients in all UR records and reports are kept confidential.

UR PLAN: REVIEW OF NEED FOR CONTINUED STAY

§ 456.231 Continued stay review required.

The UR plan must provide for a review of each recipient's continued stay in the mental hospital to decide whether it is needed, in accordance with the requirements of §§ 456.232 through 456.238.

§ 456.232 Evaluation criteria for continued stay.

The UR plan must provide that—

(a) The committee develops written medical care criteria to assess the need for continued stay.

(b) The committee develops more extensive written criteria for cases that its experience shows are—

(1) Associated with high costs;

(2) Associated with the frequent furnishing of excessive services; or

(3) Attended by physicians whose patterns of care are frequently found to be questionable.

§ 456.233 Initial continued stay review date.

The UR plan must provide that—

(a) When a recipient is admitted to the mental hospital under admission review requirements of this subpart, the committee assigns a specified date by which the need for his continued stay will be reviewed;

(b) If an individual applies for Medicaid while in the mental hospital, the committee assigns the initial continued stay review date within 1 working day after the mental hospital is notified of the application for Medicaid;

(c) The committee bases its assignment of the initial continued stay review date on—

(1) The methods and criteria required to be described under § 456.235(a);

(2) The individual's condition; and

(3) The individual's projected discharge date;

(d)(1) The committee uses any available appropriate regional medical care appraisal norms, such as those developed by abstracting services or third party payors, to assign the initial continued stay review date;

(2) These norms are based on current and statistically valid data on duration of stay in mental hospitals for patients whose characteristics, such as age and diagnosis, are similar to those of the individual whose need for continued stay is being reviewed;

(3) If the committee uses norms to assign the initial continued stay review date, the number of days between the individual's admission and the initial continued stay review date is no greater than the number of days reflected in the 50th percentile of the norms. However, the committee may assign a later review date if it documents that the later date is more appropriate;

(e) The initial continued stay review date is not in any case later than 30 days after admission of the individual or notice to the mental hospital of his application for Medicaid; and

(f) The committee insures that the initial continued stay review date is recorded in the individual's record.

§ 456.234 Subsequent continued stay review dates.

The UR plan must provide that—

(a) The committee assigns subsequent continued stay review dates in accordance with §§ 456.235(a) and 456.233;

(b) The committee assigns a subsequent continued stay review date at least every 90 days each time it decides under § 456.236 that the continued stay is needed; and

(c) The committee insures that each continued stay review date it assigns is recorded in the recipient's record.

§ 456.235 Description of methods and criteria: Continued stay review dates; length of stay modification.

The UR plan must describe—

(a) The methods and criteria, including norms if used, that the committee uses to assign initial and subsequent continued stay review dates under §§ 456.233 and 456.234 of this subpart; and

(b) The methods that the committee uses to modify an approved length of stay when the recipient's condition or treatment schedule changes.

§ 456.236 Continued stay review process.

The UR plan must provide that—

(a) Review of continued stay cases is conducted by—

(1) The UR committee;

(2) A subgroup of the UR committee; or

(3) A designee of the UR committee;

(b) The committee, subgroup or designee reviews a recipient's continued stay on or before the expiration of each assigned continued stay review date;

(c) For each continued stay of a recipient in the mental hospital, the committee, subgroup or designee reviews and evaluates the documentation described under § 456.211 against the criteria developed under § 456.232 and applies close professional scrutiny to cases described under § 456.232(b).

(d) If the committee, subgroup or designee finds that a recipient's continued stay in the mental hospital is needed, the committee assigns a new continued stay review date in accordance with § 456.234;

(e) If the committee, subgroup or designee finds that a continued stay case does not meet the criteria, the committee or a subgroup that includes at least one physician reviews the case to decide the need for continued stay;

(f) If the committee or subgroup making the review under paragraph (e) of this section finds that a continued stay is not needed, it notifies the recipient's attending or staff physician and gives him an opportunity to present his views before it makes a final decision on the need for the continued stay;

(g) If the attending or staff physician does not present additional information or clarification of the need for the continued stay, the decision of the committee or subgroup is final; and

(h) If the attending or staff physician presents additional information or clarification, at least two physician members of the committee, one of whom is knowledgeable in the treatment of mental diseases, review the need for the continued stay. If they find that the recipient no longer needs inpatient mental hospital services, their decision is final.

§ 456.237 Notification of adverse decision.

The UR plan must provide that written notice of any adverse final decision on the need for continued stay under § 456.236 (f) through (h) is sent to—

(a) The hospital administrator;

(b) The attending or staff physician;

(c) The Medicaid agency;

(d) The recipient; and

(e) If possible, the next of kin or sponsor.

§ 456.238 Time limits for final decision and notification of adverse decision.

The UR plan must provide that—

(a) The committee makes a final decision on a recipient's need for continued stay and gives notice under § 456.237 of an adverse decision within 2 working days after the assigned continued stay review date, except as required under paragraph (b) of this section.

(b) If the committee makes an adverse final decision on a recipient's need for continued stay before the assigned review date, the committee gives notice under § 456.237 within 2 working days after the date of the final decision.

UR PLAN: MEDICAL CARE EVALUATION STUDIES

§ 456.241 Purpose and general description.

(a) The purpose of medical care evaluation studies is to promote the most effective and efficient use of available health facilities and services consistent with patient needs and professionally recognized standards of health care.

(b) Medical care evaluation studies—

(1) Emphasize identification and analysis of patterns of patient care; and

(2) Suggest appropriate changes needed to maintain consistently high quality patient care and effective and efficient use of services.

§ 456.242 UR plan requirements for medical care evaluation studies.

(a) The UR plan must describe the methods that the committee uses to select and conduct medical care evaluation studies under paragraph (b)(1) of this section.

(b) The UR plan must provide that the UR committee—

(1) Determines the methods to be used in selecting and conducting medical care evaluation studies in the mental hospital;

(2) Documents for each study—

(i) Its results; and

(ii) How the results have been used to make changes to improve the quality of care and promote more effective and efficient use of facilities and services;

(3) Analyzes its findings for each study; and

(4) Takes action as needed to—

(i) Correct or investigate further any deficiencies or problems in the review process; or

(ii) Recommend more effective and efficient hospital care procedures.

§ 456.243 Content of medical care evaluation studies.

Each medical care evaluation study must—

(a) Identify and analyze medical or administrative factors related to the mental hospital's patient care;

(b) Include analysis of at least the following:

(1) Admissions.

(2) Durations of stay.

(3) Ancillary services furnished, including drugs and biologicals.

(4) Professional services performed in the hospital; and

(c) If indicated, contain recommendations for change beneficial to patients, staff, the hospital, and the community.

§ 456.244 Data sources for studies.

Data that the committee uses to perform studies must be obtained from one or more of the following sources:

(a) Medical records or other appropriate hospital data.

(b) External organizations that compile statistics, design profiles, and produce other comparative data.

(c) Cooperative endeavors with—

(1) PROs;

(2) Fiscal agents;

(3) Other service providers; or

(4) Other appropriate agencies.

[43 FR 45266, Sept. 29, 1978, as amended at 51 FR 43198, Dec. 1, 1986]

§ 456.245 Number of studies required to be performed.

The mental hospital must, at least, have one study in progress at any time and complete one study each calendar year.

Subpart E—Utilization Control: Skilled Nursing Facilities

§ 456.250 Scope.

(a) This subpart prescribes requirements for control of utilization of skilled nursing facility (SNF) services including requirements concerning—

(1) Certification of need for care;

(2) Medical evaluation and admission review;

(3) Plan of care;

(4) Utilization review plans; and

(5) Discharge plans.

§ 456.251 Definitions.

Skilled nursing facility services means those items and services defined in §§ 440.40 and 440.140 of this subchapter, but excludes those services if they are provided in Christian Science sanitoria.

Medical care criteria means predetermined elements against which aspects of the quality of a medical service may be compared. These criteria are developed by health professionals relying on their expertise and the professional health care literature.

CERTIFICATION OF NEED FOR CARE

§ 456.260 Certification and recertification of need for inpatient care.

(a) *Certification.* (1) A physician must certify for each applicant or recipient that SNF services are or were needed.

(2) The certification must be made at the time of admission or, if an individual applies for assistance while in a SNF, before the Medicaid agency authorizes payment.

(b) *Recertification.* (1) A physician, or physician assistant or nurse practitioner (as defined in § 491.2 of this chapter) acting within the scope of practice as defined by State law and under the supervision of a physician, must recertify for each applicant or recipient that SNF services are needed.

(2) Recertification must be made at least every 60 days after certification.

[46 FR 48561, Oct. 1, 1981; 46 FR 54744, Nov. 4, 1981]

MEDICAL, PSYCHIATRIC, AND SOCIAL EVALUATIONS, AND ADMISSION REVIEW

§ 456.270 Medical, psychiatric, and social evaluations.

(a) Before admission to a SNF or before authorization for payment, the attending physician must make—

(1) A medical evaluation of each applicant's or recipient's need for care in the SNF; and

(2) A plan of rehabilitation, where applicable.

(b) In a SNF that cares primarily for mental patients, appropriate professional personnel must make a psychiatric and a social evaluation of need for care.

(c) Each medical evaluation must include—

(1) Diagnoses;

(2) Summary of present medical findings;

(3) Medical history;

(4) Mental and physical functional capacity;

(5) Prognoses; and

(6) A recommendation by a physician concerning—

(i) Admission to the SNF; or

(ii) Continued care in the SNF for individuals who apply for Medicaid while in the facility.

§ 456.271 Medicaid agency review of need for admission.

Medical and other professional personnel of the Medicaid agency or its designees must evaluate each applicant's or recipient's need for admission by reviewing and assessing the evaluations required by § 456.270.

PLAN OF CARE

§ 456.280 Individual written plan of care.

(a) Before admission to a SNF or before authorization for payment, the attending physician must establish a written plan of care for each applicant or recipient in a SNF.

(b) The plan of care must include—

(1) Diagnoses, symptoms, complaints and complications indicating the need for admission;

(2) A description of the functional level of the individual;

(3) Objectives;

(4) Any orders for—

(i) Medications;

(ii) Treatments;

(iii) Restorative and rehabilitative services;

(iv) Activities;

(v) Therapies;

(vi) Social services;

(vii) Diet; and

(viii) Special procedures recommended for the health and safety of the patient;

(5) Plans for continuing care, including review and modification to the plan of care; and

(6) Plans for discharge.

(c) The attending or staff physician and other personnel involved in the recipient's care must review each plan of care at least every 60 days.

§ 456.281 Reports of evaluations and plans of care.

A written report of each evaluation and plan of care must be entered in the applicant's or recipient's record—

(a) At the time of admission; or

(b) If the individual is already in the SNF, immediately upon completion of the evaluation or plan.

UTILIZATION REVIEW (UR) PLAN: GENERAL REQUIREMENT

§ 456.300 Scope.

Sections 456.301 through 456.345 of this subpart prescribe requirements for a written utilization review (UR) plan for each SNF providing Medicaid services. Sections 456.305 and 456.306 prescribe administrative requirements; §§ 456.311 through 456.313 prescribe informational requirements; §§ 456.331 through 456.338 prescribe requirements for continued stay review; and §§ 456.341 through 456.345 prescribe requirements for medical care evaluation studies.

§ 456.301 UR plan required for skilled nursing facility services.

(a) The State plan must provide that each SNF furnishing inpatient services under the plan has in effect a written UR plan that provides for review of each recipient's need for the services that the SNF furnishes him.

(b) Each written SNF UR plan must meet the requirements under §§ 456.301 through 456.345.

UR PLAN: ADMINISTRATIVE REQUIREMENTS

§ 456.305 UR committee required.

The UR plan must—

(a) Provide for a committee to perform UR required under this subpart;

(b) Describe the organization, composition, and functions of this committee; and

(c) Specify the frequency of meetings of the committee.

§ 456.306 Organization and composition of UR committee; disqualification from UR committee membership.

(a) For the purpose of this subpart, "UR committee" includes any group organized under paragraphs (b) and (c) of this section.

(b) The UR committee must be composed of two or more physicians and assisted by other professional personnel and, in a SNF that cares primarily for mental patients, include at least one physician member who is knowledgeable in the diagnosis and treatment of mental diseases.

(c) The UR committee must be constituted as—

(1) A committee of individuals with SNF staff privileges;

(2) A group outside the SNF established by the local medical or osteopathic society and at least some of the hospitals and SNFs in the locality; or

(3) A group capable of performing utilization review and established and organized in a manner approved by the Secretary.

(d) The UR committee may not include any individual who—

(1) Is directly responsible for the care of patients whose care is being reviewed;

(2) Is employed by the SNF; or

(3) Has a financial interest in any SNF.

UR PLAN: INFORMATIONAL REQUIREMENTS

§ 456.311 Recipient information required for UR.

The UR plan must provide that each recipient's record includes information needed to perform UR required under this subpart. This information must include, at least, the following:

(a) Identification of the recipient.

(b) The name of the recipient's physician.

(c) Date of admission and dates of application for and authorization of Medicaid benefits if application is made after admission.

(d) The plan of care required under § 456.272.

(e) Initial and subsequent continued stay review dates described under §§ 456.333 and 456.334.

(f) Reasons and plan for continued stay if the attending physician believes continued stay is necessary.

(g) Other supporting material that the committee believes appropriate to be included in the record.

§ 456.312 Records and reports.

The UR plan must describe—

(a) The types of records that are kept by the committee; and

(b) The type and frequency of committee reports, and arrangements for their distribution to appropriate individuals.

§ 456.313 Confidentiality.

The UR plan must provide that the identities of individual recipients in all UR records and reports are kept confidential.

UR PLAN: REVIEW OF NEED FOR CONTINUED STAY

§ 456.331 Continued stay review required.

The UR plan must provide for a review of each recipient's continued stay in the SNF to decide whether it is needed, in accordance with the requirements of §§ 456.332-456.338.

§ 456.332 Evaluation criteria for continued stay.

The UR plan must provide that—

(a) The committee develops written medical care criteria to assess the need for continued stay; and

(b) The committee develops more extensive written criteria for cases that its experience shows are—

(1) Associated with high costs;

(2) Associated with the frequent furnishing of excessive services; or

(3) Attended by physicians whose patterns of care are frequently found to be questionable.

§ 456.333 Initial continued stay review date.

The UR plan must provide that—

(a) When a recipient is admitted to the SNF under admission review requirements of this subpart, the committee assigns a specified date by which the need for his continued stay will be reviewed;

(b) If an individual applies for Medicaid while in the SNF, the committee assigns the initial continued stay review date within one working day after the SNF is notified of the application for Medicaid;

(c) The committee bases its assignment of the initial continued stay review date on the methods and criteria required to be described under § 456.335(a);

(d) The initial continued stay review date is either—

(1) Not later than 90 days after the date of the individual's admission or notice to the SNF of his application for Medicaid, if the date is established using specific periods for diagnostic categories or categories based on functional capabilities; or

(2) Not later than 30 days after the date of the individual's admission or notice of application, if the date is established by another method; and

(e) The committee ensures that the initial continued stay review date is recorded in the individual's record.

§ 456.334 Subsequent continued stay review dates.

The UR plan must provide that—

(a) The committee assigns subsequent continued stay review dates in accordance with §§ 456.333 and 456.335(a).

(b) The committee assigns subsequent continued stay review dates each time it decides under § 456.336 that the continued stay is needed—

(1) At least every 90 days if the dates are established using specific periods for diagnostic categories based on functional capabilities; or

(2) At least every 30 days for the first 90 days and at least every 90 days thereafter if the dates are established by another method; and

(c) The committee ensures that each continued stay review date that it assigns is recorded in the recipient's record.

§ 456.335 Description of methods and criteria: Continued stay review dates; length of stay modification.

The UR plan must describe—

(a) The methods and criteria that the committee uses to assign initial and subsequent continued stay review dates under §§ 456.333 and 456.334; and

(b) The methods used by the committee to modify an approved length of stay when the recipient's condition or treatment schedule changes.

§ 456.336 Continued stay review process.

The UR plan must provide that—

(a) Review of continued stay cases is conducted by—

(1) The UR committee;

(2) A subgroup of the UR committee; or

(3) A designee of the UR committee;

(b) The committee, subgroup or designee reviews a recipient's continued stay on or before the expiration of each assigned continued stay review date;

(c) For each continued stay of a recipient in the SNF, the committee, subgroup or designee reviews and evaluates the documentation described under § 456.311 against the criteria developed under § 456.332 and applies close professional scrutiny to cases described under § 456.332(b);

(d) If the committee, subgroup or designee finds that the recipient's continued stay in the SNF is needed, the committee assigns a new continued stay review date in accordance with § 456.334;

(e) If the committee, subgroup or designee finds that a continued stay does not meet the criteria, the committee or a subgroup that includes at least one physician reviews the case to decide the need for continued stay;

(f) If the committee or subgroup making the review under paragraph (e) of this section finds that a continued stay is not needed, it notifies the recipient's attending physician and gives him an opportunity to present his views before it makes a final decision on the need for the continued stay;

(g) If the attending physician does not present additional information or clarification of the need for the continued stay, the decision of the committee of subgroup is final; and

(h) If the attending physician presents additional information or clarification, at least two physician members of the committee review the need for the continued stay. In a SNF that cares primarily for mental patients, one of these two physicians must be knowledgeable in the treatment of mental diseases. If they find that the recipient no longer needs SNF services, their decision is final.

§ 456.337 Notification of adverse decision.

The UR plan must provide that written notice of any adverse final decision on the need for continued stay under § 456.336 (f) through (h) is sent to—

(a) The SNF administrator;

(b) The attending physician;

(c) The Medicaid agency;

(d) The recipient; and

(e) If possible, the next of kin or sponsor.

§ 456.338 Time limits for final decision and notification of adverse decision.

The UR plan must provide that—

(a) The committee makes a final decision on a recipient's need for continued stay and gives notice under § 456.337 of an adverse decision within three working days after the assigned review date, except as required under paragraph (b) of the section.

(b) If the committee makes an adverse final decision on a recipient's need for continued stay before the assigned review date, the committee gives notice under § 456.337 within 2 working days after the date of the final decision.

UR PLAN: MEDICAL CARE EVALUATION STUDIES

§ 456.341 Purpose and general description.

(a) The purpose of medical care evaluation studies is to promote the most effective and efficient use of available health facilities and services consistent with patient needs and professionally recognized standards of health care.

(b) Medical care evaluation studies—

(1) Emphasize identification and analyses of patterns of patient care; and

(2) Suggest appropriate changes needed to maintain consistently high quality patient care and effective and efficient use of services.

§ 456.342 UR plan requirement for medical care evaluation studies.

(a) The UR plan must describe the methods that the committee uses to select and conduct medical care evaluation studies under paragraph (b)(1) of this section.

(b) The UR plan must provide that the UR committee—

(1) Determines the methods to be used in selecting and conducting medical care evaluation studies in the SNF;

(2) Documents for each study—

(i) Its results; and

(ii) How the results have been used to make changes to improve the quality of care and promote more effective and efficient use of facilities and services;

(3) Analyzes its findings for each study; and

(4) Takes action as needed to—

(i) Correct or investigate further any deficiencies or problems in the review process; or

(ii) Recommend more effective and efficient skilled nursing care procedures.

§ 456.343 Content of medical care evaluation studies.

Each medical care evaluation study must—

(a) Identify and analyze medical or administrative factors related to the SNFs patient care;

(b) Include analysis of at least the following:

(1) Admissions.

(2) Durations of stay.

(3) Ancillary services furnished, including drugs and biologicals.

(4) Professional services performed in the SNF; and

(c) If indicated, contain recommendations for change beneficial to patients, staff, the SNF and the community.

§ 456.344 Data sources for studies.

Data that the committee uses to perform studies must be obtained from one or more of the following sources:

(a) Medical records or other appropriate data.

(b) External organizations that compile statistics, design profiles, and produce other comparative data.

(c) Cooperative endeavors with—

(1) PROs;

(2) Fiscal agents;

(3) Other providers of services; or

(4) Other appropriate agencies.

[43 FR 45266, Sept. 29, 1978, as amended at 51 FR 43198, Dec. 1, 1986]

§ 456.345 Number of studies required to be performed.

The SNF must, at least, have one study in progress at any time and complete one study each calendar year.

DISCHARGE PLAN

§ 456.346 Discharge plan.

(a) The UR committee must review each recipient's discharge plan.

(b) Each discharge plan must insure that the recipient has a planned program of post-discharge continuing care that takes his needs into account.

§ 456.347 Discharge planning procedures.

Each SNF must maintain discharge planning procedures that describe the following:

(a) The staff member of the SNF or the health, social, or welfare agency responsible for discharge planning.

(b) The authority of the member or agency, and the methods used in discharge planning, including the relationship with the SNF's staff.

(c) The time allowed for determining each recipient's need for discharge planning. The period must not be longer than 7 days after the day of admission.

(d) The period after which each recipient's discharge plan will be reevaluated.

(e) The local resources available to the SNF, the recipient, and the attending physician to assist in developing and implementing discharge plans.

(f) The provisions for periodic review and reevaluation of the SNF's discharge planning program.

§ 456.348 Information about discharged recipients.

(a) When a recipient is discharged, the SNF must provide information that will insure the optimal continuity of care, such as—

(1) Current information relative to diagnoses;

(2) Prior treatment;

(3) Rehabilitation potential;

(4) Physician advice concerning immediate care; and

(5) Pertinent social information.

(b) This information must be provided to those persons who are responsible for the recipient's post-discharge care.

Subpart F—Utilization Control: Intermediate Care Facilities

§ 456.350 Scope.

This subpart prescribes requirements for control of utilization of intermediate care facility (ICF) services including requirements concerning—

(a) Certification of need for care;

(b) Medical evaluation and admission review;

(c) Plan of care; and

(d) Utilization review plans.

§ 456.351 Definition.

As used in this subpart:

Intermediate care facility services means those items and services furnished in an intermediate care facility as defined in §§ 440.140 and 440.150 of this subchapter, but excludes those services if they are provided in Christian Science sanitoria.

CERTIFICATION OF NEED FOR CARE

§ 456.360 Certification and recertification of need for inpatient care.

(a) *Certification.* (1) A physician must certify for each applicant or recipient that ICF services are or were needed.

(2) The certification must be made at the time of admission or, if an individual applies for assistance while in an ICF, before the Medicaid agency authorizes payment.

(b) *Recertification.* (1) A physician, or physician assistant or nurse practitioner (as defined in § 491.2 of this chapter) acting within the scope of practice as defined by State law and under the supervision of a physician, must recertify for each applicant or recipient that ICF services are needed.

(2) Recertification must be made at least—

(i) Every 12 months after certification in an institution for the mentally retarded or persons with related conditions; and

(ii) Every 60 days after certification in an ICF other than an institution for the mentally retarded or persons with related conditions.

[46 FR 48561, Oct. 1, 1981, as amended at 50 FR 33034, Aug. 16, 1985]

MEDICAL, PSYCHOLOGICAL, AND SOCIAL EVALUATIONS AND ADMISSION REVIEW

§ 456.370 Medical, psychological, and social evaluations.

(a) Before admission to an ICF or before authorization for payment, an interdisciplinary team of health professionals must make a comprehensive medical and social evaluation and, where appropriate, a psychological evaluation of each applicant's or recipient's need for care in the ICF.

(b) In an institution for the mentally retarded or persons with related conditions, the team must also make a psychological evaluation of need for care. The psychological evaluation must be made before admission or authorization of payment, but not more than three months before admission.

(c) Each evaluation must include—

(1) Diagnoses;

(2) Summary of present medical, social, and where appropriate, developmental findings;

(3) Medical and social family history;

(4) Mental and physical functional capacity;

(5) Prognoses;

(6) Kinds of services needed;

(7) Evaluation by an agency worker of the resources available in the home, family and community; and

(8) A recommendation concerning—

(i) Admission to the ICF; or

(ii) Continued care in the ICF for individuals who apply for Medicaid while in the ICF.

§ 456.371 Exploration of alternative services.

If the comprehensive evaluation recommends ICF services for an applicant or recipient whose needs could be met by alternative services that are currently unavailable, the facility must enter this fact in the recipient's record and begin to look for alternative services.

§ 456.372 Medicaid agency review of need for admission.

Medical and other professional personnel of the Medicaid agency or its designees must evaluate each applicant's or recipient's need for admission by reviewing and assessing the evaluations required by § 456.370.

Plan of Care

§ 456.380 Individual written plan of care.

(a) Before admission to an ICF or before authorization for payment, a physician must establish a written plan of care for each applicant or recipient.

(b) The plan of care must include—

(1) Diagnoses, symptoms, complaints, and complications indicating the need for admission;

(2) A description of the functional level of the individual;

(3) Objectives;

(4) Any orders for—

(i) Medications;

(ii) Treatments;

(iii) Restorative and rehabilitative services;

(iv) Activities;

(v) Therapies;

(vi) Social services;

(vii) Diet; and

(viii) Special procedures designed to meet the objectives of the plan of care;

(5) Plans for continuing care, including review and modification of the plan of care; and

(6) Plans for discharge.

(c) The team must review each plan of care at least every 90 days.

§ 456.381 Reports of evaluations and plans of care.

A written report of each evaluation and plan of care must be entered in the applicant's or recipient's record—

(a) At the time of admission; or

(b) If the individual is already in the ICF, immediately upon completion of the evaluation or plan.

Utilization Review (UR) Plan: General Requirement

§ 456.400 Scope.

Sections 456.401 through 456.438 of this subpart prescribe requirements for a written utilization review (UR) plan for each ICF providing Medicaid services. Sections 456.405 through 456.407 prescribe administrative requirements; §§ 456.411 through 456.413 prescribe informational requirements; and §§ 456.431 through 456.438 prescribe requirements for continued stay review.

§ 456.401 State plan UR requirements and options; UR plan required for intermediate care facility services.

(a) The State plan must provide that—

(1) UR is performed for each ICF that furnishes inpatient services under the plan;

(2) Each ICF has on file a written UR plan that provides for review of each recipient's need for the services that the ICF furnishes him; and

(3) Each written ICF UR plan meets requirements under §§ 456.401 through 456.438.

(b) The State plan must specify the method used to perform UR, which may be—

(1) Review conducted by the facility;

(2) Direct review in the facility by individuals—

(i) Employed by the medical assistance unit of the Medicaid agency; or

(ii) Under contract to the Medicaid agency; or

(3) Any other method.

UR PLAN: ADMINISTRATIVE REQUIREMENTS

§ 456.405 Description of UR review function: How and when.

The UR plan must include a written description of—

(a) How UR is performed in the ICF; and

(b) When UR is performed.

§ 456.406 Description of UR review function: Who performs UR; disqualification from performing UR.

(a) The UR plan must include a written description of who performs UR in the ICF.

(b) UR must be performed using a method specified under § 456.401(b) by a group of professional personnel that includes—

(1) At least one physician;

(2) In an ICF that cares primarily for mental patients, at least one individual knowledgeable in the treatment of mental diseases; and

(3) In an institution for the mentally retarded, a least one individual knowledgeable in the treatment of mental retardation.

(c) The group performing UR may not include any individual who—

(1) Is directly responsible for the care of the recipient whose care is being reviewed;

(2) Is employed by the ICF; or

(3) Has a financial interest in any ICF.

§ 456.407 UR responsibilities of administrative staff.

The UR plan must describe—

(a) The UR support responsibilities of the ICF's administrative staff; and

(b) Procedures used by the staff for taking needed corrective action.

UR PLAN: INFORMATIONAL REQUIREMENTS

§ 456.411 Recipient information required for UR.

The UR plan must provide that each recipient's record include information needed to perform UR required under this subpart. This information must include, at least, the following:

(a) Identification of the recipient.

(b) The name of the recipient's physician.

(c) The name of the qualified mental retardation professional (as defined under § 442.401 of this subchapter), if applicable.

(d) Date of admission, and dates of application for and authorization of Medicaid benefits if application is made after admission.

(e) The plan of care required under § 456.372;

(f) Initial and subsequent continued stay review dates described under §§ 456.433 and 456.434.

(g) Reasons and plan for continued stay, if the attending physician or qualified mental retardation professional believes continued stay is necessary.

(h) Other supporting material that the UR group believes appropriate to be included in the record.

§ 456.412 Records and reports.

The UR plan must describe—

(a) The types of records that are kept by the group performing UR; and

(b) The type and frequency of reports made by the UR group, and arrangements for distribution of the reports to appropriate individuals.

§ 456.413 Confidentiality.

The UR plan must provide that the identities of individual recipients in all UR records and reports are kept confidential.

UR PLAN: REVIEW OF NEED FOR CONTINUED STAY

§ 456.431 Continued stay review required.

(a) The UR plan must provide for a review of each recipients continued stay in the ICF at least every 6 months to decide whether it is needed.

(b) The UR plan requirement for continued stay review may be met by—

(1) Reviews that are performed in accordance with the requirements of §§ 456.432 through 456.437; or

(2) Reviews that meet on-site inspection requirements under Subpart I if—

(i) The composition of the independent professional review team under Subpart I meets the requirements of § 456.406; and

(ii) Reviews are conducted as frequently as required under §§ 456.433 and 456.434.

§ 456.432 Evaluation criteria for continued stay.

The UR plan must provide that—

(a) The group performing UR develops written criteria to assess the need for continued stay.

(b) The group develops more extensive written criteria for cases that its experience shows are—

(1) Associated with high costs;

(2) Associated with the frequent furnishing of excessive services; or

(3) Attended by physicians whose patterns of care are frequently found to be questionable.

§ 456.433 Initial continued stay review date.

The UR plan must provide that—

(a) When a recipient is admitted to the ICF under admission review requirements of this subpart, the group performing UR assigns a specified date by which the need for his continued stay will be reviewed;

(b) The group performing UR bases its assignment of the initial continued stay review date on the methods and criteria required to be described under § 456.435(a);

(c) The initial continued stay review date is—

(1) Not later than 6 months after admission; or

(2) Earlier than 6 months after admission, if indicated at the time of admission; and

(d) The group performing UR insures that the initial continued stay review date is recorded in the recipient's record.

§ 456.434 Subsequent continued stay review dates.

The UR plan must provide that—

(a) The group performing UR assigns subsequent continued stay review dates in accordance with § 456.435.

(b) The group assigns a subsequent continued stay review date each time it decides under § 456.436 that the continued stay is needed—

(1) At least every 6 months; or

(2) More frequently than every six months if indicated at the time of continued stay review; and

(c) The group insures that each continued stay review date it assigns is recorded in the recipient's record.

§ 456.435 Description of methods and criteria: Continued stay review dates.

The UR plan must describe the methods and criteria that the group performing UR uses to assign initial and subsequent continued stay review dates under §§ 456.433 and 456.434.

§ 456.436 Continued stay review process.

The UR plan must provide that—

(a) Review of continued stay cases is conducted by—

(1) The group performing UR; or

(2) A designee of the UR group;

(b) The group or its designee reviews a recipient's continued stay on or before the expiration of each assigned continued stay review date.

(c) For each continued stay of a recipient in the ICF, the group or its designee reviews and evaluates the documentation described under § 456.411 against the criteria developed under § 456.432 and applies close professional scrutiny to cases described under § 456.432(b);

(d) If the group or its designee finds that a recipient's continued stay in the ICF is needed, the group assigns a new continued stay review date in accordance with § 456.434;

(e) If the group or its designee finds that a continued stay case does not meet the criteria, the group or a subgroup that includes at least one physician reviews the case to decide the need for continued stay;

(f) If the group or subgroup making the review under paragraph (e) of this section finds that a continued stay is not needed, it notifies the recipient's attending physician or, in institutions for the mentally retarded, the recipient's qualified mental retardation professional, within 1 working day of its decision, and gives him 2 working days from the notification date to present his views before it makes a final decision on the need for the continued stay;

(g) If the attending physician or qualified mental retardation professional does not present additional information or clarification of the need for the continued stay, the decision of the UR group is final;

(h) If the attending physician or qualified mental retardation professional presents additional information or clarification, the need for continued stay is reviewed by—

(1) The physician member(s) of the UR group, in cases involving a medical determination; or

(2) The UR group, in cases not involving a medical determination; and

(i) If the individuals performing the review under paragraph (h) of this section find that the recipient no longer needs ICF services, their decision is final.

§ 456.437 Notification of adverse decision.

The UR plan must provide that written notice of any adverse final decision on the need for continued stay under § 456.436 (g) through (i) is sent to—

(a) The ICF administrator;

(b) The attending physician;

(c) The qualified mental retardation professional, if applicable;

(d) The Medicaid agency;

(e) The recipient; and

(f) If possible, the next of kin or sponsor.

§ 456.438 Time limits for notification of adverse decision.

The UR plan must provide that the group gives notice under § 456.437 of an adverse decision not later than 2 days after the date of the final decision.

Subpart G—Inpatient Psychiatric Services for Individuals Under Age 21: Admission and Plan of Care Requirements

§ 456.480 Scope.

This subpart concerns admission and plan of care requirements that apply to inpatient psychiatric services for individuals under age 21 in hospitals, mental hospitals, skilled nursing facilities, and intermediate care facilities.

§ 456.481 Admission certification and plan of care.

If a facility provides inpatient psychiatric services to a recipient under age 21—

(a) The admission certification by the review team required in § 441.152 satisfies the requirement for physician certification of need for care in §§ 456.60, 456.160, 456.260, and 456.360; and

(b) The development and review of the plan of care required in § 441.154 satisfies the requirement for physician recertification of need for care in the sections cited in paragraph (a) and the requirement for establishment and periodic review of the plan of care in §§ 456.80, 456.180, 456.280, and 456.380.

(c) The plan of care must be established by the team described in § 441.156.

§ 456.482 Medical, psychiatric, and social evaluations.

If a facility provides inpatient psychiatric services to a recipient under age 21, the medical, psychiatric, and social evaluations required by §§ 456.170, 456.270, and 456.370 must be made by the team described in § 441.153.

Subpart H—Utilization Review Plans: FFP, Waivers, and Variances for Hospitals, Mental Hospitals, and Skilled Nursing Facilities

§ 456.500 Purpose.

For hospitals, mental hospitals and SNFs, this subpart—

(a) Prescribes conditions for the availability of FFP relating to UR plans;

(b) Prescribes conditions for granting a waiver of UR plan requirements; and

(c) Prescribes conditions for granting a variance in UR plan requirements for remote facilities.

§ 456.501 UR plans as a condition for FFP.

(a) Except when waived under §§ 456.505 through 456.508, FFP is not available in expenditures for Medicaid services furnished by a hospital, mental hospital, or SNF unless the facility has in effect a UR plan that meets the utilization review requirements for Medicare under section 1861(k) of the Act.

(b) A facility that participates in Medicare and Medicaid must use the same UR standards and procedures and review committee for Medicaid as it uses for Medicare.

(c) A facility that does not participate in Medicare must meet the UR plan requirements in Subpart C, D, or E of this part, which are equivalent to the Medicare UR plan requirements in §§ 405.1137, 482.30, and 482.60 of this chapter.

[43 FR 45266, Sept. 29, 1978, as amended at 51 FR 22042, June 17, 1986]

UR PLAN: WAIVER OF REQUIREMENTS

§ 456.505 Applicability of waiver.

The Administrator may waive the UR plan requirements of Subparts C, D, or E of this part, except for provisions relating to disqualification of UR committee members under § 456.106 of Subpart C, § 456.206 of Subpart D, and § 456.306 of Subpart E, if the Medicaid agency—

(a) Applies for a waiver; and

(b) Demonstrates to the Administrator's satisfaction that it has in operation specific UR procedures that are superior in their effectiveness to the UR plan requirements under Subparts C, D, or E.

§ 456.506 Waiver options for Medicaid agency.

(a) The agency may apply for a waiver at any time it has the procedures referred to under § 456.505(b) in operation at least—

(1) On a demonstration basis; or

(2) In any part of the State.

(b) Any hospital, mental hospital, or SNF participating under the plan that is not covered by a waiver must continue to meet all the UR plan requirements under Subpart C, D, or E of this part.

§ 456.507 Review and granting of waiver requests.

(a) When the agency applies for a waiver, the Administrator will assess the agency's UR procedures and grant the waiver if he determines that the procedures meet criteria he establishes.

(b) The Administrator will review and evaluate each waiver between 1 and 2 years after he has granted it and between 1 and 2 years periodically thereafter.

§ 456.508 Withdrawal of waiver.

(a) The Administrator will withdraw a waiver if he determines that State procedures are no longer superior in their effectiveness to the procedures required for UR plans under Subparts C, D, or E.

(b) If a waiver is withdrawn by the Administrator, each hospital, mental hospital, or SNF covered by the waiver must meet all the UR plan requirements under Subparts C, D, or E of this part.

UR PLAN: REMOTE FACILITY VARIANCES FROM TIME REQUIREMENTS

§ 456.520 Definitions.

As used in §§ 456.521 through 456.525 of this subpart:

Available physician or other professional personnel means an individual who—

(a) Is professionally qualified;

(b) Is not precluded from participating in UR under § 456.107 of Subpart C; § 456.207 of Subpart D; or § 456.307 of Subpart E; and

(c) Is not precluded from effective participation in UR because he requires more than approximately 1 hour to travel between the remote facility and his place of work.

Remote facility means a facility located in an area that does not have enough available physicians or other professional personnel to perform UR as required under Subparts C, D, or E of this part, and for which the State requests a variance.

Variance means permission granted by the Administrator to the Medicaid agency for a specific remote facility to use time periods different from those specified for the start and completion of reviews of all cases under the following sections: §§ 456.125, 456.126, 456.136, and 456.137 of Subpart C; § 456.238 of Subpart D; and §§ 456.333, 456.334, and 456.336 of Subpart E.

§ 456.521 Conditions for granting variance requests.

(a) Except as described under paragraph (b) of this section, the administrator may grant a variance for a specific remote facility if the agency submits concurrently—

(1) A request for the variance that documents to his satisfaction that the facility is unable to meet the time requirements for which the variance is requested; and

(2) A revised UR plan for the facility.

(b) The Administrator will not grant a variance if the remote facility is operating under a UR plan waiver that the Secretary has granted or is considering under §§ 456.505 through 456.508.

§ 456.522 Content of request for variance.

The agency's request for a variance must include—

(a) The name, location, and type of the remote facility;

(b) The number of total patient admissions and the average daily patient census at the facility in the 6 months preceding the request;

(c) The number of Medicare and Medicaid patient admissions and the average daily Medicare and Medicaid patient census at the facility in the 6 months preceding the request;

(d) The name and location of each hospital, mental hospital, SNF, and ICF located within a 50-mile radius of the facility;

(e) The distance and average travel time between the remote facility and each facility listed in paragraph (e) of this section;

(f) Documentation by the facility of its attempts to obtain the services of available physicians or other professional personnel, or both;

(g) The names of all physicians on the active staff, and the names of all other professional personnel on the staff whose availability is relevant to the request;

(h) The practice locations of available physicians and the estimated number of available professional personnel whose availability is relevant to the request;

(i) Documentation by the facility of its inability to perform UR within the time requirements for which the variance is requested and its good faith efforts to comply with the UR plan requirements of Subparts C, D, or E of this part;

(j) An assurance by the facility that it will continue its good faith efforts to meet the UR plan requirements of Subpart C, D, or E of this part; and

(k) A statement of whether a planning or conditional PSRO exists in the area where the facility is located.

§ 456.523 Revised UR plan.

(a) The revised UR plan for the remote facility must specify the methods and procedures that the facility will use if a variance is granted to insure that it—

(1) Maintains effective and timely control over the utilization of services; and

(2) Conducts reviews in a way that improves the quality of care provided to patients.

(b) The revised UR plan for the remote facility is the basis for validation of UR under sec. 1903(g)(2) of the Act for the period when a variance is in effect.

§ 456.524 Notification of Administrator's action and duration of variance.

(a) The Administrator—

(1) Will notify the agency of the action he takes on its request for a variance; and

(2) Will specify the period of time, not to exceed 1 year, for which the variance may be granted.

(b) When it receives the Administrator's notification, the agency must promptly notify the remote facility of his action.

§ 456.525 Request for renewal of variance.

(a) The agency must submit a request for renewal of a variance to the Administrator at least 30 days before the variance expires.

(b) The renewal request must contain the information required under § 456.522.

(c) The renewal request must show, to the Administrator's satisfaction, that the remote facility continues to meet the requirements of §§ 456.521 through 456.523.

Subpart I—Inspections of Care in Skilled Nursing and Intermediate Care Facilities and Institutions for Mental Diseases

§ 456.600 Purpose.

This subpart prescribes requirements for periodic inspections of care and services in skilled nursing facilities (SNF's), intermediate care facilities (ICF's), and institutions for mental diseases (IMD's).

§ 456.601 Definitions.

For purposes of this subpart—

Facility means a skilled nursing facility, an institution for mental diseases, or an intermediate care facility.

Intermediate care facility includes institutions for the mentally retarded or persons with related conditions but excludes Christian Science sanatoria operated, or listed and certified, by the First Church of Christ Scientist, Boston, Mass.

Institution for mental diseases includes a mental hospital, a psychiatric facility, and a skilled nursing or intermediate care facility that primarily cares for mental patients.

Psychiatric facility includes a facility or program that provides inpatient psychiatric services for individuals under 21, as specified in § 441.151 of this chapter, but does not include psychiatric wards in acute care hospitals.

[44 FR 56337, Oct. 1, 1979]

§ 456.602 Inspection team.

(a) A team, as described in this section and § 456.603 must periodically inspect the care and services provided to recipients in each facility.

(b) Each team conducting periodic inspections must have a least one member who is at physician or registered nurse and other appropriate health and social service personnel.

(c) For an IMD other than an ICF, each team must have a psychiatrist or physician knowledgeable about mental institutions and other appropriate mental health and social service personnel.

(d) For an ICF that primarily cares for mental patients, each team must have at least one member who knows the problems and needs of mentally retarded individuals.

(e) For an institution for the mentally retarded or persons with related conditions, each team must have at least one member who knows the problems and needs of mentally retarded individuals.

(f) For ICFs primarily serving individuals 65 years of age or older, each team must have at least one member who knows the problems and needs of those individuals.

(g) If there is no physician on the team, the Medicaid agency must insure that a physician is available to provide consultation to the team.

(h) If a team has one or more physicians, it must be supervised by a physician.

§ 456.603 Financial interests and employment of team members.

(a) Except as provided in paragraph (b) of this section—

(1) No member of a team that reviews care in a SNF may have a financial interest in or be employed by any SNF; and

(2) No member of a team that reviews care in an ICF may have a financial interest in or be employed by any ICF.

(b) A member of a team that reviews care in an IMD or an institution for the mentally retarded or persons with related conditions—

(1) May not have a financial interest in any institution of that same type but may have a financial interest in other facilities or institutions; and

(2) May not review care in an institution where he is employed but may review care in any other facility or institution.

§ 456.604 Physician team member inspecting care of recipients.

No physician member of a team may inspect the care of a recipient for whom he is the attending physician.

§ 456.605 Number and location of teams.

There must be a sufficient number of teams so located within the State that onsite inspections can be made at appropriate intervals in each facility caring for recipients.

§ 456.606 Frequency of inspections.

The team and the agency must determine, based on the quality of care and services being provided in a facility and the condition of recipients in the facility, at what intervals inspections will be made. However, the team must inspect the care and services provided to each recipient in the facility at least annually.

§ 456.607 Notification before inspection.

No facility may be notified of the time of inspection more than 48 hours before the scheduled arrival of the team.

§ 456.608 Personal contact with and observation of recipients and review of records.

(a) For recipients under age 21 in psychiatric facilities and recipients in SNFs and ICFs, other than those described in paragraph (b) of this section, the team's inspection must include—

(1) Personal contact with and observation of each recipient; and

(2) Review of each recipient's medical record.

(b) For recipients age 65 or older in IMDs, the team's inspection must include—

(1) Review of each recipient's medical record; and

(2) If the record does not contain complete reports of periodic assessments required by § 441.102 of this subchapter or, if such reports are inadequate, personal contact with and observation of each recipient

[43 FR 45266, Sept. 29, 1978, as amended at 44 FR 17940, Mar. 23, 1979]

§ 456.609 Determinations by team.

The team must determine in its inspection whether—

(a) The services available in the facility are adequate to—

(1) Meet the health needs of each recipient, and the rehabilitative and social needs of each recipient in an ICF; and

(2) Promote his maximum physical, mental, and psychosocial functioning.

(b) It is necessary and desirable for the recipient to remain in the facility;

(c) It is feasible to meet the recipient's health needs and, in an ICF, the recipient's rehabilitative needs, through alternative institutional or noninstitutional services; and

(d) Each recipient under age 21 in a psychiatric facility and each recipient in an institution for the mentally retarded or persons with related conditions is receiving active treatment as defined in § 441.154 of this subchapter.

§ 456.610 Basis for determinations.

In making the determinations on adequacy of services and related matters under § 456.609 for each recipient, the team may consider such items as whether—

(a) The medical evaluation, any required social and psychological evaluations, and the plan of care are complete and current; the plan of care and, where required, the plan of rehabilitation are followed; and all ordered services, including dietary orders, are provided and properly recorded;

(b) The attending physician reviews prescribed medications—

(1) At least every 30 days in SNFs, psychiatric facilities, and mental hospitals; and

(2) At least quarterly in ICFs;

(c) Tests or observations of each recipient indicated by his medication regimen are made at appropriate times and properly recorded;

(d) Physician, nurse, and other professional progress notes are made as required and appear to be consistent with the observed condition of the recipient;

(e) The recipient receives adequate services, based on such observations as—

(1) Cleanliness;

(2) Absence of bedsores;

(3) Absence of signs of malnutrition or dehydration; and

(4) Apparent maintenance of maximum physical, mental, and psychosocial funtion;

(f) In an ICF, the recipient receives adequate rehabilitative services, as evidenced by—

(1) A planned program of activities to prevent regression; and

(2) Progress toward meeting objectives of the plan of care;

(g) The recipient needs any service that is not furnished by the facility or through arrangements with others; and

(h) The recipient needs continued placement in the facility or there is an appropriate plan to transfer the recipient to an alternate method of care.

§ 456.611 Reports on inspections.

(a) The team must submit a report promptly to the agency on each inspection.

(b) The report must contain the observations, conclusions, and recommendations of the team concerning—

(1) The adequacy, appropriateness, and quality of all services provided in the facility or through other arrangements, including physician services to recipients; and

(2) Specific findings about individual recipients in the facility.

(c) The report must include the dates of the inspection and the names and qualifications of the members of the team.

[43 FR 45266, Sept. 29, 1978, as amended at 44 FR 56337, Oct. 1, 1979]

§ 456.612 Copies of reports.

The agency must send a copy of each inspection report to—

(a) The facility inspected;

(b) The facility's utilization review committee;

(c) The agency responsible for licensing, certification, or approval of the facility for purposes of Medicare and Medicaid; and

(d) Other State agencies that use the information in the reports to perform their official function, including, if inspection reports concern IMD's, the appropriate State mental health authorities.

§ 456.613 Action on reports.

The agency must take corrective action as needed based on the report and recommendations of the team submitted under this subpart.

§ 456.614 Inspections by utilization review committee.

A utilization review committee under Subparts C through F of this part may conduct the periodic inspections required by this subpart if—

(a) The committee is not based in the facility being reviewed; and

(b) The composition of the committee meets the requirements of this subpart.

Subpart J—Penalty for Failure To Make a Satisfactory Showing of an Effective Institutional Utilization Control Program

AUTHORITY: Secs. 1102 and 1903(g) of the Social Security Act (42 U.S.C. 1302 and 1396b(g)).

SOURCE: 44 FR 56338, Oct. 1, 1979, unless otherwise noted.

§ 456.650 Basis, purpose and scope.

(a) *Basis.* Section 1903(g) of the Act requires that FFP for long-stay inpatient services at a level of care be reduced, by a specified formula, for any quarter in which a State fails to make a satisfactory showing that it has an effective program of utilization control for that level of care.

(b) *Purpose.* This subpart specifies—

(1) What States must do to make a satisfactory showing;

(2) How the Administrator will determine whether reductions will be imposed; and

(3) How the required reductions will be implemented.

(c) *Scope.* The reductions required by this subpart do not apply to—

(1) Services provided under a contract with a health maintenance organization; or

(2) Facilities in which a PRO is performing medical and utilization re-

views under contract with the Medicaid agency in accordance with § 431.630 of this chapter.

[44 FR 56338, Oct. 1, 1979, as amended at 50 FR 15327, Apr. 17, 1985; 51 FR 43198, Dec. 1, 1986]

§ 456.651 Definitions.

For purposes of this subpart—

Facility, with respect to inpatient psychiatric services for individuals under 21, includes a psychiatric program as specified in § 441.151 of this chapter.

Level of care means one of the following types of inpatient services: hospital, mental hospital, skilled nursing facility, intermediate care facility, or psychiatric services for individuals under 21.

Long-stay services means services provided to a recipient after a total of 60 days of inpatient stay (90 in the case of mental hospital services) during a 12-month period beginning July 1, not counting days of stay paid for wholly or in part by Medicare.

§ 456.652 Requirements for an effective utilization control program.

(a) *General requirements.* In order to avoid a reduction in FFP, the Medicaid agency must make a satisfactory showing to the Administrator, in each quarter, that it has met the following requirements for each recipient:

(1) Certification and recertification of the need for inpatient care, as specified in §§ 456.60, 456.160, 456.260, 456.360 and 456.481.

(2) A plan of care established and periodically reviewed and evaluated by a physician, as specified in §§ 456.80, 456.180, 456.280, 456.380 and 456.481.

(3) A continuous program of utilization review under which the admission of each recipient is reviewed or screened in accordance with section 1903(g)(1)(C) of the Act; and

(4) A regular program of reviews, including medical evaluations, and annual on-site reviews of the care of each recipient, as specified in §§ 456.170, 456.270, 456.370, and 456.482 and Subpart I of this part.

(b) *Annual on-site review requirements.* (1) An agency meets the quarterly on-site review requirements of paragraph (a)(4) of this section for a quarter if it completes on-site reviews of each recipient in every facility in the State, and in every State-owned facility regardless of location, by the end of the quarter in which a review is required under paragraph (b)(2) of this section.

(2) An on-site review is required in a facility by the end of a quarter if the facility entered the Medicaid program during the same calendar quarter 1 year earlier or has not been reviewed since the same calendar quarter 1 year earlier. If there is no Medicaid recipient in the facility on the day a review is scheduled, the review is not required until the next quarter in which there is a Medicaid recipient in the facility.

(3) If a facility is not reviewed in the quarter in which it is required to be reviewed under paragraph (b)(2) of this section, it will continue to require a review in each subsequent quarter until the review is performed.

(4) The requirement for an on-site review in a given quarter is not affected by the addition or deletion of a level of care in a facility's provider agreement.

(c) *Facilities without valid provider agreements.* The requirements of paragraphs (a) and (b) of this section apply with respect to recipients for whose care the agency intends to claim FFP even if the recipients receive care in a facility whose provider agreement has expired or been terminated.

[44 FR 56338, Oct. 1, 1979, as amended at 46 FR 48561, Oct. 1, 1981]

§ 456.653 Acceptable reasons for not meeting requirements for annual on-site review.

The Administrator will find an agency's showing satisfactory, even if it failed to meet the annual review requirements of §456.652(a)(4), if—

(a) The agency demonstrates that—

(1) It completed reviews by the end of the quarter in at least 98 percent of all facilities requiring review by the end of the quarter;

(2) It completed reviews by the end of the quarter in all facilities with 200 or more certified Medicaid beds requiring review by the end of the quarter; and

(3) With respect to all unreviewed facilities, the agency exercised good faith and due diligence by attempting to review those facilities and would have succeeded but for events beyond its control which it could not have reasonably anticipated; or

(b) The agency demonstrates that it failed to meet the standard in paragraph (a) (1) and (2) of this section by the close of the quarter for technical reasons, but met the standard within 30 days after the close of the quarter. Technical reasons are circumstances within the agency's control.

(c) Facilities that are reviewed under paragraph (b) of this section, after the quarter in which they were due for review, retain their original anniversary quarter due date for purposes of subsequent reviews.

§ 456.654 Requirements for content of showings and procedures for submittal.

(a) An agency's showing for a quarter must—

(1) Include a certification by the agency that the requirements of § 456.652(a) (1) through (4) were met during the quarter for each level of care or, if applicable, a certification of the reasons the annual on-site review requirements of § 456.652(a)(4) were not met in any facilities;

(2) For all mental hospitals, skilled nursing facilities, intermediate care facilities, and facilities providing inpatient psychiatric services for individuals under 21, participating in Medicaid any time during the 12-month period ending on the last day of the quarter, list each facility by level of care, name, address and provider number;

(3) For each facility entering or leaving the program during the 12-month period ending on the last day of the quarter, list the beginning or ending dates of the provider agreement and supply a copy of the provider agreement;

(4) If review has been contracted to a PRO under § 431.630 of this chapter, list the date the PRO contracted for review.

(5) List all dates of on-site reviews completed by review teams anytime during the 12-month period ending on the last day of the quarter;

(6) For all facilities in which an onsite review was required but not conducted, list the facility by name, address and provider number;

(7) For each on-site review in a mental hospital, skilled nursing or intermediate care facility that primarily cares for mental patients, or inpatient psychiatric facility, list the name and qualifications of one team member who is a physician; and

(8) For each on-site review in an intermediate care facility or skilled nursing facility that does not primarily care for mental patients, list the name and qualifications of one team member who is either a physician or registered nurse.

(b) The quarterly showing must be in the form prescribed by the Administrator.

(c) The quarterly showing must be postmarked or received within 30 days after the close of the quarter for which it is made, unless the agency demonstrates good cause for later submittal and the showing is postmarked or received within 45 days after the close of the quarter. Good cause means unanticipated circumstances beyond the agency's control.

[44 FR 56338, Oct. 1, 1979, as amended at 50 FR 15327, Apr. 17, 1985; 51 FR 43198, Dec. 1, 1986]

§ 456.655 Validation of showings.

(a) The Administrator will periodically validate showings submitted under § 456.654. Validation procedures will include on-site sample surveys of institutions and surveys at the Medicaid agencies.

(b) The Administrator will not find an agency's showing satisfactory if the information obtained through his validation procedures demonstrates, that any of the requirements of § 456.652(a) (1) through (4) were not met during the quarter for which the showing was made.

§ 456.656 Reductions in FFP.

(a) If the Administrator determines an agency's showing does not meet each of the requirements of this subpart, he will give the agency 30 days notice before making the required reduction.

(b) If the Administrator determines that a showing for any quarter is unsatisfactory on its face, he will make the required reduction in the grant award based on the Quarterly Statement of Expenditures for that quarter. (See § 430.30(c) of this chapter.)

(c) If the Administrator finds a showing satisfactory on its face, but after validation determines the showing to be unsatisfactory, he will notify the agency of any required reduction in FFP no later than the first day of the fourth calendar quarter following the calendar quarter for which the showing was made. Any required reduction will be made by amending or adjusting the agency's grant award.

(d) The agency may request reconsideration of a reduction in accordance with the procedures specified in 45 CFR Part 16.

§ 456.657 Computation of reductions in FFP.

(a) For each level of care specified in a provider agreement, and for each quarter for which a satisfactory showing is not made, the amount of the reduction in FFP is computed as follows:

(1) For each level of care, the number of recipients who received services in facilities that did not meet the requirements of this subpart is divided by the total number of recipients who received services in facilities for which a showing was required under this subpart. If any of the requirements specified in § 456.652(a)(1) through (4) were not met for any recipient in a facility, the reduction will be computed on the total number of recipients in that facility at the level of care in question.

(2) The fraction obtained in paragraph (a)(1) of this section is multiplied by one-third.

(3) The product obtained in paragraph (a)(2) of this section is multiplied by the Federal Medical Assistance Percentage (FMAP).

(4) The product obtained in paragraph (a)(3) of this section is multiplied by the agency payments for long-stay services furnished during the quarter at that level of care.

(b) If any of the data required to compute the amount of the reduction in FFP are unavailable, the Administrator will substitute an estimate. If the agency determines the exact data to the satisfaction of the Administrator, the estimate may later be adjusted. If the number of recipients in individual facilities is not available, the fraction specified in paragraph (a)(1) of this section will be estimated, for each level of care, by dividing the number of facilities in which the requirements were not met by the total number of facilities for which a showing is required under this subpart.

SUBCHAPTER D—PEER REVIEW ORGANIZATIONS

PART 462—PEER REVIEW ORGANIZATIONS

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462.107 PRO contract award.

AUTHORITY: Secs. 1102, 1152, and 1153 of the Social Security Act (42 U.S.C. 1302, 1320c-1 and 1320-2).

Subpart A—General Provisions

§ 462.1 Definitions.

For purposes of this part:

Five percent or more owner means a person (including, where appropriate, a corporation) who:

(a) Has an ownership interest of 5 percent or more;

(b) Has an indirect ownership interest equal to 5 percent or more;

(c) Has a combination of direct and indirect ownership interests (the possession of equity in the capital, the stock, or the profits of an entity) equal to 5 percent or more; or

(d) Is the owner of an interest of 5 percent or more in any obligation secured by an entity, if the interest equals at least 5 percent of the value of the property or assets of the entity.

Health care facility means an institution that directly provides or supplies health care services for which payment may be made in whole or in part under Title XVIII of the Act. A health care facility may be a hospital, skilled nursing facility, home health agency, free-standing ambulatory surgical center, or outpatient facility or any other entity which provides or supplies direct care to Medicare beneficiaries.

Managing employee means a general manager, business manager, administrator, director or other individual who exercises operational or managerial control over the entity or organization, or who, directly or indirectly, conducts the day-to-day operations of the entity or organization.

Payor organization means any organization, other than a self-insured employer, which makes payments directly or indirectly to health care practitioners or providers whose health care services are reviewed by the organization or would be reviewed by the organization if it entered into a PRO contract. "Payor organization" also means any organization which is affiliated with any entity which makes payments as described above, by virtue of the organization having two or more governing body members who are also either governing body members, officers, partners, 5 percent or more owners or managing employees in a health maintenance organization or competitive medical plan.

Physician means:

(1) A doctor of medicine or osteopathy licensed under State law to practice medicine, surgery, or osteopathy in the State in which the PRO is located;

(2) An intern, resident, or Federal Government employee authorized under State or Federal law to practice medicine, surgery, or osteopathy in the PRO area; and

(3) An individual licensed to practice medicine in American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands.

[43 FR 32085, July 24, 1978, as amended at 49 FR 7206, Feb. 27, 1984. Redesignated at 50 FR 15327, Apr. 17, 1985, and amended at 50 FR 15328, Apr. 17, 1985; 51 FR 43197, Dec. 1, 1986]

Subpart B—[Reserved]

Subpart C—Utilization and Quality Control Peer Review Organizations

SOURCE: 49 FR 7207, Feb. 27, 1984, unless otherwise noted. Redesignated at 50 FR 15327, Apr. 17, 1985.

§ 462.100 Scope and applicability.

This subpart implements sections 1152 and 1153(b) of the Social Security Act as amended by the Peer Review Improvement Act of 1982 (Pub. L. 97-248). It defines the types of organizations eligible to become PROs and establishes certain limitations and priorities regarding PRO contracting.

§ 462.101 Eligibility requirements for PRO contracts.

In order to be eligible for a PRO contract an organization must—

(a) Be either a physician-sponsored organization as described in § 462.102; or a physician-access organization as described in § 462.103; and

(b) Demonstrate its ability to perform review as set forth in § 462.104.

§ 462.102 Eligibility of physician-sponsored organizations.

(a) In order to be eligible for designation as a physician-sponsored PRO, an organization must meet the following conditions:

(1) Be composed of a substantial number of the licensed doctors of medicine and osteopathy practicing medicine or surgery in the review area and who are representative of the physicians practicing in the area.

(2) Not be a health care facility, health care facility association, or health care facility affiliate, as specified in § 462.105.

(b) In order to meet the requirements of paragraph (a)(1) of this section, an organization must state and have documentation in its files showing that it is composed of at least 10 percent of the licensed doctors of medicine and osteopathy practicing medicine or surgery in the review area.

(c) In order to meet the requirements or paragraph (a)(2) of this section, an organization must—

(1) State and have documentation in its files demonstrating that it is composed of at least 20 percent of the licensed doctors of medicine and osteopathy practicing medicine or surgery in the review area; or

(2) If the organization is not composed of at least 20 percent of the licensed doctors of medicine and osteopathy practicing medicine or surgery in the review area, then the organization must demonstrate in its contract proposal, through letters of support from physicians or physician organizations, or through other means, that it is representative of the area physicians.

(d) Organizations that meet the requirements in paragraph (a) of this section will receive, during the contract evaluation process, a set number of bonus points.

[49 FR 7207, Feb. 27, 1984. Redesignated at 50 FR 15327, Apr. 17, 1985 and amended at 50 FR 15328, Apr. 17, 1985]

§ 462.103 Eligibility of physician-access organizations.

(a) In order to be eligible for designation as a physician-access PRO, an organization must meet the following conditions:

(1) Have available to it, by arrangement or otherwise, the services of a sufficient number of licensed doctors of medicine or osteopathy practicing medicine or surgery in the review area to assure adequate peer review of the services provided by the various medical specialties and subspecialties.

(2) Not be a health care facility, health care facility association, or health care facility affiliate, as specified in § 462.105.

(b) An organization meets the requirements of paragraph (a)(1) of this section if it demonstrates—

(1) That it has available to it at least one physician in every generally recognized specialty; and

(2) The existence of an arrangement or arrangements with physicians under which the physicians would conduct review for the organization.

[50 FR 15328, Apr. 17, 1985]

§ 462.104 Requirements for demonstrating ability to perform review.

(a) A physician-sponsored or physician-access organization will be found capable of conducting review if HCFA determines that the organization is able to set quantifiable performance objectives and perform the utilization and quality review functions established under section 1154 of the Social Security Act in an efficient and effective manner.

(b) HCFA will determine that the organization is capable of conducting utilization and quality review if—

(1) The organization's proposed review system is adequate; and

(2) The organization has available sufficient resources (including access to medical review skills) to implement that system; and

(3) The organization's quantifiable objectives are acceptable.

(c) HCFA may consider prior similar review experience in making determinations under paragraph (b) of this section.

(d) A State government that operates a Medicaid program will be considered incapable of performing utilization and quality review functions in an effective manner, unless the State demonstrates to the satisfaction of HCFA that it will act with complete independence and objectivity.

§ 462.105 Prohibition against contracting with health care facilities.

(a) *Basic rule.* Except as permitted under paragraph (b) of this section, the following are not eligible for PRO contracts:

(1) A health care facility in the PRO area.

(2) An association of health care facilities in the PRO area.

(3) A health care facility affiliate; that is, an organization in which more than 20 percent of the members of the governing body are also either a governing body member, officer, partner, five percent or more owner, or managing employee in a health care facility or association of health care facilities in the PRO area.

(b) *Exceptions.* Effective November 15, 1984, the prohibition stated in paragraph (a) of this section will not apply to a payor organization if HCFA determines under § 462.106 that there is no other eligible organization available.

(c) *Subcontracting.* A PRO must not subcontract with a facility to conduct any review activities except for the review of the quality of care.

[50 FR 15328, Apr. 17, 1985]

§ 462.106 Prohibition against contracting with payor organizations.

Payor organizations are not eligible to become PROs for the area in which they make payments until November 15, 1984. If no PRO contract for an area is awarded before November 15, 1984, a payor organization will be determined eligible by HCFA, if an eligible organization that is not a payor organization is unavailable at that time. HCFA may determine the unavailability of nonpayor organizations based on the lack of response to an appropriate Request for Proposal.

[50 FR 15328, Apr. 17, 1985]

§ 462.107 PRO contract award.

HCFA, in awarding PRO contracts, will take the following actions—

(a) Identify from among all proposals submitted in response to an RFP for a given PRO area all proposals submitted by organizations that meet the requirements of § 462.102 or § 462.103;

(b) Identify from among all proposals identified in paragraph (a) of this section all proposals that set forth minimally acceptable plans in accordance with the requirements of § 462.104 and the RFPs;

(c) Assign bonus points not to exceed 10% of the total points available to all physician-sponsored organizations identified in paragraph (b) of this section, consistent with statute; and

(d) Subject to the limitations established by §§ 462.105 and 462.106, award the contract for the given PRO area to the selected organization for a period of two years.

[49 FR 7207, Feb. 27, 1984. Redesignated and amended at 50 FR 15327, 15328, Apr. 17, 1985]

PART 466—UTILIZATION AND QUALITY CONTROL REVIEW

Subpart A—General Provisions

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Subpart B—[Reserved]

Subpart C—Review Responsibilities of Utilization and Quality Control Peer Review Organizations (PROs)

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PRO REVIEW FUNCTIONS

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466.104 Coordination of activities.

AUTHORITY: Secs. 1102, 1154, and 1871 of the Social Security Act (42 U.S.C. 1302, 1320c-3 and 1395hh).

SOURCE: 44 FR 32081, June 4, 1979, unless otherwise noted.

Subpart A—General Provisions

§ 466.1 Definitions.

As used in this part, unless the context indicates otherwise:

Active staff privileges means: (a) That a physician is authorized on a regular, rather than infrequent or courtesy, basis: (1) to order the admission of patients to a facility; (2) to perform diagnostic services in a facility; or (3) to care for and treat patients in a facility; or (b) that a health care practitioner other than a physician is authorized on a regular, rather than infrequent or courtesy, basis to order the admission of patients to a facility.

Admission review means a review and determination by a PRO of the medical necessity and appropriateness of a patient's admission to a specific facility.

Continued stay review means PRO review that is performed after admission review and during a patient's hospitalization to determine the medical necessity and appropriateness of continuing the patient's stay at a hospital level of care.

Criteria means predetermined elements of health care, developed by health professionals relying on professional expertise, prior experience, and the professional literature, with which aspects of the quality, medical necessity, and appropriateness of a health care service may be compared.

Diagnosis related group (DRG) means a system for classifying inpatient hospital discharges. DRGs are used for purposes of determining payment to hospitals for inpatient hospital services under the Medicare prospective payment system.

DRG validation means a part of the prospective payment system in which a PRO validates that DRG assignments are based on the correct diagnostic and procedural information.

Elective, when applied to admission or to a health care service, means an admission or a service that can be delayed without substantial risk to the health of the individual.

Five percent or more owner means a person (including, where appropriate, a corporation) who:

(a) Has an ownership interest of 5 percent or more;

(b) Has an indirect ownership interest equal to 5 percent or more;

(c) Has a combination of direct and indirect ownership interests (the possession of equity in the capital, the stock, or the profits of an entity) equal to five percent or more; or

(d) Is the owner of an interest of five percent or more in any obligation secured by an entity, if the interest equals at least five percent of the value of the property or assets of the entity.

Health care facility or *facility* means an organization involved in the delivery of health care services for which reimbursement may be made in whole or in part under Title XVIII of the Act.

Health care practitioners other than physicians means those health professionals who do not hold a doctor of medicine or doctor of osteopathy degree, who meet all applicable State or Federal requirements for practice of their professions, and who are in active practice.

Hospital means a health care institution or distinct part of a health care institution, as defined in Section 1861(e)-(g) of the Act, other than a Christian Science sanatorium operated, or listed and certified, by the First Church of Christ, Scientist, Boston, Massachusetts.

Initial denial determination means an initial negative decision by a PRO, regarding the medical necessity, quality, or appropriateness of health care services furnished, or proposed to be furnished, to a patient.

Major clinical area means medicine, surgery, pediatrics, obstetrics and gynecology, or psychiatry.

Major procedure means a diagnostic or therapeutic procedure which involves a surgical or anesthetic risk or requires highly trained personnel or special facilities or equipment.

Non-facility organization means a corporate entity that (1) is not a health care facility; (2) is not a 5 percent or more owner of a facility; and (3) is not owned by one or more health care facilities or association of facilities in the PRO area.

Norm means a pattern of performance in the delivery of health care services that is typical for a specified group.

Norms means numerical or statistical measures of average observed performance in the delivery of health care services.

Outliers means those cases that have either an extremely long length of stay or extraordinarily high costs when compared to most discharges classified in the same DRG.

Peer review means review by health care practitioners of services ordered or furnished by other practitioners in the same professional field.

Physician means a doctor of medicine or osteopathy or another individual who is authorized under State or Federal law to practice medicine and surgery, or osteopathy. This includes medical officers in American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands.

Practitioner means an individual credentialed within a recognized health care discipline and involved in providing the services of that discipline to patients.

Preadmission certification means a favorable determination, transmitted to the hospital and the fiscal intermediary, approving the patient's admission for payment purposes.

Preadmission review means review prior to a patient's admission to a hospital to determine, for payment purposes, the reasonableness, medical necessity and appropriateness of placement at an acute level of care.

Preprocedure review means review of a surgical or other invasive procedure prior to the conduct of the procedure.

PRO review means review performed in fulfillment of a contract with HCFA, either by the PRO or its subcontractors.

Profile means aggregated data in formats that display patterns of health care services over a defined period of time.

Profile analysis means review and analysis of profiles to identify and consider patterns of health care services.

Quality review study means an assessment conducted by or for a PRO of a patient care problem for the purpose of improving patient care through peer analysis, intervention, resolution of the problem and follow-up.

Regional norms, criteria, and standards means norms, criteria, and standards that apply to a geographic division which is larger than a PRO area.

Retrospective review means review that is conducted after services are provided to a patient. The review is focused on determining the appropriateness, necessity, quality, and reasonableness of health care services provided.

Review responsibility means (1) the responsibility of the PRO to perform review functions prescribed under Part B of Title XI of the Act and the Social Security Amendments of 1983 (Pub. L. No. 98-21) and the regulations of this part; (2) the responsibility to fulfill the terms and meet the objectives set forth in the negotiated contract between HCFA and the PRO; and (3) the authority of a PRO to make conclusive initial denial determinations regarding the medical necessity and appropriateness of health care and changes as a result of DRG validations.

Skilled nursing facility (SNF) means a health care institution or distinct part of an institution that (a) is primarily engaged in providing skilled nursing care or rehabilitative services to injured, disabled, or sick persons, and (b) has an agreement to participate in Medicare or Medicaid or both, and (c) is not a Christian Science sanatorium operated or listed and certified by the First Church of Christ Scientist, Boston, Massachusetts.

Standards means professionally developed expressions of the range of acceptable variation from a norm or criterion.

Subcontractor means a facility or a non-facility organization under contract with a PRO to perform PRO review functions.

Working day means any one of at least five days of each week (excluding, at the option of each PRO, legal holidays) on which the necessary personnel are available to perform review.

[44 FR 32081, June 4, 1979, as amended at 45 FR 67545, Oct. 10, 1980; 46 FR 48569, Oct. 1, 1981. Redesignated and amended at 50 FR 15328, 15329, Apr. 17, 1985; 51 FR 43197, Dec. 1, 1986]

Subpart B—[Reserved]

Subpart C—Review Responsibilities of Utilization and Quality Control Peer Review Organizations (PROs)

SOURCE: 50 FR 15330, Apr. 17, 1985, unless otherwise noted.

GENERAL PROVISIONS

§ 466.70 Statutory bases and applicability.

(a) *Statutory basis.* Sections 1154, 1866(a)(1)(F) and 1886(f)(2) of the Act require that a PRO review those services furnished by physicians, other health care professionals, providers and suppliers as specified in its contract with the Secretary. Section 1154(a)(4) of the Act requires PROs, or, in certain circumstances, non-PRO entities, to perform quality of care reviews of services furnished under risk-basis contracts by health maintenance organizations (HMOs) and competitive medical plans (CMPs) that are covered under Subpart C of Part 417 of this chapter.

(b) *Applicability.* The regulations in this subpart apply to review conducted by a PRO and its subcontractors. Section 466.72 of this part also applies, for purposes of quality of care reviews under section 1154(a)(4) of the Act, to non-PRO entities that enter into contracts to perform reviews of services furnished under risk-basis contracts by HMOs and CMPs under Subpart C of Part 417 of this chapter.

[52 FR 37457, Oct. 7, 1987]

§ 466.71 PRO review requirements.

(a) *Scope of PRO review.* In its review, the PRO must determine (in accordance with the terms of its contract)—

(1) Whether the services are or were reasonable and medically necessary for the diagnosis and treatment of ill-

ness or injury or to improve functioning of a malformed body member, or (with respect to pneumococcal vaccine) for prevention of illness or (in the case of hospice care) for the palliation and management of terminal illness;

(2) Whether the quality of the services meets professionally recognized standards of health care;

(3) Whether those services furnished or proposed to be furnished on an inpatient basis could, consistent with the provisions of appropriate medical care, be effectively furnished more economically on an outpatient basis or in an inpatient health care facility of a different type;

(4) Through DRG validation, the validity of diagnostic and procedural information supplied by the hospital;

(5) The completeness, adequacy and quality of hospital care provided;

(6) The medical necessity, reasonableness and appropriateness of hospital admissions and discharges;

(7) The medical necessity, reasonableness and appropriateness of inpatient hospital care for which additional payment is sought under the outlier provisions of §§ 412.82 and 412.84 of this chapter; and

(8) Whether a hospital has misrepresented admission or discharge information or has taken an action that results in—

(i) The unnecessary admission of an individual entitled to benefits under Part A;

(ii) Unnecessary multiple admissions of an individual; or

(iii) Other inappropriate medical or other practices with respect to beneficiaries or billing for services furnished to beneficiaries.

(b) *Payment determinations.* On the basis of the review specified under paragraphs (a) (1), (3), (6), (7), and (8) of this section, the PRO must determine whether payment may be made for these services. A PRO may grant a period of not more than two days (grace days) for the purpose of arranging post discharge care when the provider did not know or could not reasonably be expected to have known that payment for the service(s) would not be made under the Medicare program as specified in § 405.330(b).

(c) *Other duties and functions.* (1) The PRO must review at least a random sample of hospital discharges each quarter and submit new diagnostic and procedural information to the Medicare fiscal intermediary or carrier if it determines that the information submitted by the hospital was incorrect.

(2) The PRO must review every change in a DRG assignment that is a result of a review made under the provisions of § 412.60 (d) if the change results in the assignment of a higher-weighted DRG and the PRO has not previously reviewed the case. The PRO must verify that the diagnostic and procedural information supplied by the hospital is substantiated by the information in the medical record.

(d) *Coordination of sanction activities.* The PRO must carry out the responsibilities specified in Subpart C of Part 1004 of this title regarding imposition of sanctions on providers and practitioners who violate their statutory obligations under section 1156 of the Act.

[52 FR 37457, Oct. 7, 1987; 52 FR 47003, Dec. 11, 1987]

§ 466.72 Review of the quality of care of risk-basis health maintenance organizations and competitive medical plans.

(a) (1) For purposes of a review under section 1154(a)(4) of the Act, a PRO must determine whether the quality of services (including both inpatient and outpatient services) provided by an HMO or CMP meets professionally recognized standards of health care, including whether appropriate health care services have not been provided or have been provided in inappropriate settings.

(2) Paragraph (a)(1) of this section will not apply with respect to a contract year if another entity has been awarded a contract to perform those reviews under section 1154(a)(4)(C) of the Act.

(b) For purposes of reviews under this section, non-PRO entities selected to perform these reviews under section 1154(a)(4)(C) of the Act are subject to the requirements of paragraph (a)(1) of this section and—

(1) Part 476 of this chapter regarding acquisition, protection, and disclosure of peer review information; and

(2) Part 1004 of Chapter V regarding a PRO's responsibilities, and sanctions on health care practitioners and providers.

[52 FR 37457, Oct. 7, 1987]

§ 466.73 Notification of PRO designation and implementation of review.

(a) *Notice of HCFA's decision.* HCFA sends written notification of a PRO contract award to the State survey agency and Medicare fiscal intermediaries and carriers. The notification includes the effective dates of the PRO contract and specifies the area and types of health care facilities to be reviewed by the PRO. The PRO must make a similar notification when review responsibilities are subcontracted.

(b) *Notification to health care facilities and the public.* As specified in its contract with HCFA, the PRO must—

(1) Provide, to each health care facility scheduled to come under review, a timely written notice that specifies the date and manner in which the PRO proposes to implement review, and the information to be furnished by the facility to each Medicare beneficiary upon admission as specified in § 466.78(b)(3) of this part.

(2) Publish, in at least one local newspaper of general circulation in the PRO area, a notice that states the date the PRO will assume review responsibilities and lists each area health care facility to be under review. The PRO must indicate that its plan for the review of health care services as approved in its contract with HCFA is available for public inspection in the PRO's business office and give the address, telephone number and usual hours of business.

[50 FR 15330, Apr. 17, 1985. Redesignated at 52 FR 37457, Oct. 7, 1987]

§ 466.74 General requirements for the assumption of review.

(a) A PRO must assume review responsibility in accordance with the schedule, functions and negotiated objectives specified in its contract with HCFA.

(b) A PRO must notify the appropriate Medicare fiscal intermediary or carrier of its assumption of review in specific health care facilities no later than five working days after the day that review is assumed in the facility.

(c) A PRO must maintain and make available for public inspection at its principal business office—

(1) A copy of each agreement with Medicare fiscal intermediaries and carriers;

(2) A copy of its currently approved review plan that includes the PRO's method for implementing review; and

(3) Copies of all subcontracts for the conduct of review.

(d) A PRO must not subcontract with a facility to conduct any review activities except for the review of the quality of care. The PRO may subcontract with a non-facility organization to conduct review in a facility.

(e) If required by HCFA, a PRO is responsible for compiling statistics based on the criteria contained in § 405.332 of this chapter and making limitation of liability determinations on excluded coverage of certain services that are made under section 1879 of the Act. If required by HCFA, PROs must also notify a provider of these determinations. These determinations and further appeals are governed by the reconsideration and appeals procedures in Part 405, Subpart G of this chapter for Medicare Part A related determinations and Part 405, Subpart H of this chapter for Medicare Part B related determinations.

(f) A PRO must make its responsibilities under its contract with HCFA, primary to all other interests and activities that the PRO undertakes.

§ 466.76 Cooperation with health care facilities.

Before implementation of review, a PRO must make a good faith effort to discuss the PRO's administrative and review procedures with each involved health care facility.

§ 466.78 Responsibilities of health care facilities.

(a) Beginning November 15, 1984, every hospital seeking payment for services provided to Medicare benefici-

best copy available

aries must maintain a written agreement with a PRO operating in the area in which the hospital is located. These agreements must provide for the PRO review specified in § 466.70(c).

(b) *Cooperation with PROs.* Health care facilities that submit Medicare claims must cooperate in the assumption and conduct of PRO review. Facilities must—

(1) Allocate adequate space to the PRO for its conduct of review at the times the PRO is conducting review.

(2) Provide patient care data and other pertinent data to the PRO at the time the PRO is collecting review information that is required for the PRO to make its determinations. When review is performed away from the facility, the facility must photocopy and deliver to the PRO, without charge, all required information within 30 days of a request. When the PRO does post-admission, preprocedure review, the facility must provide the necessary information before the procedure is performed, unless it must be performed on an emergency basis.

(3) Inform Medicare beneficiaries at the time of admission, in writing, that the care for which Medicare payment is sought will be subject to PRO review and indicate the potential outcomes of that review. Furnishing this information to the patient does not constitute notice, under § 405.332(a) of this chapter, that can support a finding that the beneficiary knew the services were not covered.

(4) When the facility has issued a written determination in accordance with § 412.42(c)(3) of this chapter that a beneficiary no longer requries inpatient hospital care, it must submit a copy of its determination to the PRO within 3 working days.

(5) Assure, in accordance with the provisions of its agreement with the PRO, that each case subject to preadmission review has been reviewed and approved by the PRO before admission to the hospital or a timely request has been made for PRO review.

(6)(i) Agree to accept financial liability for any admission subject to preadmission review that was not reviewed by the PRO and is subsequently determined to be inappropriate or not medically necessary.

(ii) The provisions of paragraph (b)(6)(i) of this section do not apply if a facility, in accordance with its agreement with a PRO, makes a timely request for preadmission review and the PRO does not review the case timely. Cases of this type are subject to retrospective prepayment review under paragraph (b)(7) of this section.

(7) Agree that, if the hospital admits a case subject to preadmission review without certification, the case must receive retrospective prepayment review, according to the review priority established by the PRO.

§ 466.80 Coordination with Medicare fiscal intermediaries and carriers.

(a) *Procedures for agreements.* The Medicare fiscal intermediary or carrier must have a written agreement with the PRO. The PRO must take the initiative with the fiscal intermediary or carrier in developing the agreement. The following steps must be taken in developing the agreement.

(1) The PRO and the fiscal intermediary or carrier must negotiate in good faith in an effort to reach written agreement. If they cannot reach agreement, HCFA will assist them in resolving matters in dispute.

(2) The PRO must incorporate its administrative procedures into an agreement with the fiscal intermediary or carrier and obtain approval from HCFA, before it makes conclusive determinations for the Medicare program, unless HCFA finds that the fiscal intermediary or carrier has—

(i) Refused to negotiate in good faith or in a timely manner, or

(ii) Insisted on including in the agreement, provisions that are outside the scope of its authority under the Act.

(b) *Content of agreement.* The agreement must include procedures for—

(1) Informing the appropriate Medicare fiscal intermediaries and carriers of—

(i) Changes as a result of DRG validations and revisions as a result of the review of these changes; and

(ii) Initial denial determinations and revisions of these determinations as a result of reconsideration, or reopening all approvals and denials with respect to cases subject to preadmission review, and outlier claims in hospitals under a prospective payment system for health care services and items;

(2) Exchanging data or information;

(3) Modifying the procedures when additional review responsibility is authorized by HCFA; and

(4) Any other matters that are necessary for the coordination of functions.

(c) *Action by HCFA.* (1) Within the time specified in its contract, the PRO must submit to HCFA for approval its agreement with the Medicare fiscal intermediaries and carriers, or if an agreement has not been established, the PRO's proposed administrative procedures, including any comments by the Medicare fiscal intermediaries and carriers.

(2) If HCFA approves the agreement or the administrative procedures (after a finding by HCFA as specified in paragraph (a)(2) of this section), the PRO may begin to make determinations under its contract with HCFA.

(3) If HCFA disapproves the agreement or procedures, it will—

(i) Notify the PRO and the appropriate fiscal agents in writing, stating the reasons for disapproval; and

(ii) Require the PRO and fiscal intermediary or carrier to revise its agreements or procedures.

(d) *Modification of agreements.* Agreements or procedures may be modified, with HCFA's approval—

(1) Through a revised agreement with the fiscal intermediary or carrier, or

(2) In the case of procedures, by the PRO, after providing opportunity for comment by the fiscal intermediary or carrier.

(e) *Role of the fiscal intermediary.* (1) The fiscal intermediary will not pay any claims for those cases which are subject to preadmission review by the PRO, until it receives notice that the PRO has approved the admission after preadmission or retrospective review.

(2) A PRO's determination that an admission is medically necessary is not a guarantee of payment by the fiscal intermediary. Medicare coverage requirements must also be applied.

[50 FR 15330, Apr. 17, 1985; 50 FR 41886, Oct. 16, 1985]

§ 466.82 Continuation of functions not assumed by PROs.

Any of the duties and functions under Part B of Title XI of the Act for which a PRO has not assumed responsibility under its contract with HCFA must be performed in the manner and to the extent otherwise provided for under the Act or in regulations.

PRO REVIEW FUNCTIONS

§ 466.83 Initial denial determinations.

A determination by a PRO that the health care services furnished or proposed to be furnished to a patient are not medically necessary, are not reasonable, or are not at the appropriate level of care, is an initial denial determination and is appealable under Part 473 of this chapter.

§ 466.84 Changes as a result of DRG validation.

A provider or practitioner may obtain a review by a PRO under Part 473 of this chapter for changes in diagnostic and procedural coding that resulted in a change in DRG assignment as a result of PRO validation activities.

§ 466.85 Conclusive effect of PRO initial denial determinations and changes as a result of DRG validations.

A PRO initial denial determination or change as a result of DRG validation is final and binding unless, in accordance with the procedures in Part 473—

(a) The initial denial determination is reconsidered and revised; or

(b) The change as a result of DRG validation is reviewed and revised.

§ 466.86 Correlation of Title XI functions with Title XVIII functions.

(a) *Payment determinations.* (1) PRO initial denial determinations under this part with regard to the reasonableness, medical necessity, and appropriateness of placement at an acute level of patient care as are also conclusive for payment purposes with regard to the following medical issues:

(i) Whether inpatient care furnished in a psychiatric hospital meets the requirements of § 424.14 of this chapter.

(ii) Whether payment for inpatient hospital or SNF care beyond 20 consecutive days is precluded under § 489.50 of this chapter because of failure to perform review of long-stay cases.

(iii) Whether the care furnished was custodial care or care not reasonable and necessary and, as such, excluded under § 405.310(g) or § 405.310(k) of this chapter.

(iv) Whether the care was appropriately furnished in the inpatient or outpatient setting.

(2) Reviews with respect to determinations listed in paragraph (a)(1) of this section must not be conducted, for purposes of payment, by Medicare fiscal intermediaries or carriers except as outlined in paragraph (c) of this section.

(3) PROs make determinations as to the appropriateness of the location in which procedures are performed. A procedure may be medically necessary but denied if the PRO determines that it could, consistent with the provision of appropriate medical care, be effectively provided more economically on an outpatient basis or in an inpatient health care facility of a different type.

(4) PRO determinations as to whether the provider and the beneficiary knew or could reasonably be expected to have known that the services described in paragraph (a)(1) of this section were excluded are also conclusive for payment purposes.

(b) *Utilization review activities.* PRO review activities to determine whether inpatient hospital or SNF care services are reasonable and medically necessary and are furnished at the appropriate level of care fulfill the utilization review requirements set forth in §§ 405.1035, 405.1042, and 405.1137 of this chapter.

(c) *Coverage.* Nothing in paragraphs (a) (1) and (3) of this section will be construed as precluding HCFA or a Medicare fiscal intermediary or carrier, in the proper exercise of its duties and functions, from reviewing claims to determine:

(1) In the case of items or services not reviewed by a PRO, whether they meet coverage requirements of Title XVIII relating to medical necessity, reasonableness, or appropriateness of placement at an acute level of patient care. However, if a coverage determination pertains to medical necessity, reasonableness, or appropriateness of placement at an acute level of patient care, the fiscal intermediary or carrier must use a PRO to make a determination on those issues if a PRO is conducting review in the area and must abide by the PRO's determination.

(2) Whether any claim meets coverage requirements of Title XVIII relating to issues other than medical necessity, reasonableness or appropriateness of placement at an acute level of patient care.

(d) *Payment.* Medicare fiscal intermediaries and carriers are not precluded from making payment determinations with regard to coverage determinations made under paragraph (c) of this section.

(e) *Survey, compliance and assistance activities.* PRO review and monitoring activities fulfill the requirements for compliance and assistance activities of State survey agencies under section 1864(a) with respect to sections 1861(e)(6), 1861(j)(8), 1861(j)(12), and 1861(k) of the Act, and activities required of intermediaries and carriers under §§ 421.100(d) and 421.200(f) of this chapter.

(f) *Appeals.* The requirements and procedures for PRO review of changes as a result of DRG validation and the reconsideration, hearing and judicial review of PRO initial denial determinations are set forth in Part 473 of this chapter.

[50 FR 15330, Apr. 17, 1985; 50 FR 41886, Oct. 16, 1985, as amended at 53 FR 6648, Mar. 2, 1988]

§ 466.88 Examination of the operations and records of health care facilities and practitioners.

(a) *Authorization to examine records.* A facility claiming Medicare payment must permit a PRO or its subcontractor to examine its operation and records (including information on charges) that are pertinent to health care services furnished to Medicare beneficiaries and are necessary for the PRO or its subcontractor to—

(1) Perform review functions including, but not limited to—

(i) DRG validation;

(ii) Outlier review in facilities under a prospective payment system; and

(iii) Implementation of corrective action and fraud and abuse prevention activities;

(2) Evaluate cases that have been identified as deviating from the PRO norms and criteria, or standards; and

(3) Evaluate the capability of the facility to perform quality review functions under a subcontract with the PRO.

(b) *Limitations on access to records.* A PRO has access to the records of non-Medicare patients if—

(1) The records relate to review performed under a non-Medicare PRO contract and if authorized by those patients in accordance with State law; or

(2) The PRO needs the records to perform its quality review responsibilities under the Act and receives authorization from the facility or practitioner.

(c) *Conditions of examination.* When examining a facility's operation or records the PRO must—

(1) Examine only those operations and records (including information on charges) required to fulfill the purposes of paragraph (a) of this section;

(2) Cooperate with agencies responsible for other examination functions under Federal or Federally assisted programs in order to minimize duplication of effort;

(3) Conduct the examinations during reasonable hours; and

(4) Maintain in its principal office written records of the results of the examination of the facility.

§ 466.90 Lack of cooperation by a health care facility or practitioner.

(a) If a health care facility or practitioner refuses to allow a PRO to enter and perform the duties and functions required under its contract with HCFA, the PRO may—

(1) Determine that the health care facility or practitioner has failed to comply with the requirements of § 474.30(c) of this chapter and report the matter to the HHS Inspector General; or

(2) Issue initial denial determinations for those claims it is unable to review, make the determination that financial liability will be assigned to the health care facility, and report the matter to the HHS Inspector General.

(b) If a PRO provides a facility with sufficient notice and a reasonable amount of time to respond to a request for information about a claim, and if the facility does not respond in a timely manner, the PRO will deny the claim.

§ 466.93 Opportunity to discuss proposed initial denial determination and changes as a result of a DRG validation.

Before a PRO reaches an initial denial determination or makes a change as a result of a DRG validation, it must—

(a) Promptly notify the provider or supplier and the patient's attending physician (or other attending health care practitioner) of the proposed determination or DRG change; and

(b) Afford an opportunity for the provider or supplier and the physician (or other attending health care practitioner) to discuss the matter with the PRO physician advisor and to explain the nature of the patient's need for health care services, including all factors which preclude treatment of the patient as an outpatient or in an alternative level of inpatient care.

§ 466.94 Notice of PRO initial denial determination and changes as a result of a DRG validation.

(a) *Notice of initial denial determination*—(1) *Parties to be notified.* A PRO must provide written notice of an initial denial determination to—

(i) The patient, or if the patient is expected to be unable to comprehend the notice, the patient's next of kin, guardian or other representative or sponsor;

(ii) The attending physician, or other attending health care practitioner;

(iii) The facility; and

(iv) The fiscal intermediary or carrier.

(2) *Timing of the notice.* The notice must be delivered to beneficiaries in the facility or mailed to those no longer in the facility, within the following time periods—

(i) For admission, on the first working day after the initial denial determination;

(ii) For continued stay (e.g., outliers in facilities under a prospective payment system), by the first working day after the initial denial determination if the beneficiary is still in the facility, and within 3 working days if the beneficiary has been discharged;

(iii) For preprocedure review, before the procedure is performed;

(iv) For preadmission review, before admission;

(v) If identification as a Medicare program patient has been delayed, within three working days of identification;

(vi) For retrospective review, (excluding DRG validation and post procedure review), within 3 working days of the initial denial determination; and

(vii) For post-procedure review, within 3 working days of the initial denial determination.

(3) *Preadmission review.* In the case of preadmission review, the PRO must document that the patient and the facility received notice of the initial denial determination.

(b) *Notice of changes as a result of a DRG validation.* The PRO must notify the provider and practitioner of changes to procedural and diagnostic information that result in a change of DRG assignment, within 30 days of the PRO's decision.

(c) *Content of the notice.* The notice must be understandable and written in plain English and must contain—

(1) The reason for the initial denial determination or change as a result of the DRG validation;

(2) For day outliers in hospitals, the date on which the stay or services in the facility will not be approved as being reasonable and medically necessary or appropriate to the patients' health care needs;

(3) A statement informing each party or his or her representative of the right to request in accordance with the provisions of Part 473, Subpart B of this chapter—

(i) Review of a change resulting from DRG validation; or

(ii) Reconsideration of the initial denial determination;

(4) The locations for filing a request for reconsideration or review and the time period within which a request must be filed;

(5) A statement about who is liable for payment of the denied services under section 1879 of the Act; and

(6) A statement concerning the duties and functions of the PRO under the Act.

(d) *Notice to payers.* The PRO must provide prompt written notice of an initial denial determination or changes as a result of a DRG validation to the Medicare fiscal intermediary or carrier within the same time periods as the notices to the other parties.

(e) *Record of initial denial determination and changes as a result of a DRG validation.* (1) The PRO must document and preserve a record of all initial denial determinations and changes as a result of DRG validations for six years from the date the services in question were provided.

(2) The documentary record must include—

(i) The detailed basis for the initial denial determination or changes as a result of a DRG validation; and

(ii) A copy of the determination or change in DRG notices sent to all parties and identification of each party and the date on which the notice was mailed or delivered.

§ 466.96 Review period and reopening of initial denial determinations and changes as a result of DRG validations.

(a) *General timeframe.* A PRO or its subcontractor—

(1) Within one year of the date of the claim containing the service in question, may review and deny payment; and

(2) Within one year of the date of its decision, may reopen an initial denial determination or a change as a result of a DRG validation.

(b) *Extended timeframes.* (1) An initial denial determination or change as a result of a DRG validation may be made after one year but within four years of the date of the claim containing the service in question, if HCFA approves.

(2) A reopening of an initial denial determination or change as a result of a DRG validation may be made after one year but within four years of the date of the PRO's decision if—

(i) Additional information is received on the patient's condition;

(ii) Reviewer error occurred in interpretation or application of Medicare coverage policy or review criteria;

(iii) There is an error apparent on the face of the evidence upon which the initial denial or DRG validation was based; or

(iv) There is a clerical error in the statement of the initial denial determination or change as a result of a DRG validation.

(c) *Fraud and abuse.* (1) A PRO or its subcontractor may review and deny payment anytime there is a finding that the claim for service involves fraud or a similar abusive practice that does not support a finding of fraud.

(2) An initial denial determination or change as a result of a DRG validation may be reopened and revised anytime there is a finding that it was obtained through fraud or a similar abusive practice that does not support a finding of fraud.

§ 466.98 Reviewer qualifications and participation.

(a) *Peer review by physician.* (1) Except as provided in paragraph (a)(2) of this section, each person who makes an initial denial determination about services furnished or proposed to be furnished by a licensed doctor of medicine or osteopathy or by a doctor of dentistry must be respectively another licensed doctor of medicine or osteopathy or of dentistry with active staff privileges in one or more hospitals in the PRO area.

(2) If a PRO determines that peers are not available to make initial denial determinations, a doctor of medicine or osteopathy may make denial determinations for services ordered or performed by a doctor in any of the three specialties.

(3) For purposes of paragraph (a)(1) of this section, individuals authorized to practice medicine in American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands as "medical officers" may make determinations on care ordered or furnished by their peers but not on care ordered or furnished by licensed doctors of medicine or osteopathy.

(b) *Peer review by health care practitioners other than physicians.* Health care practitioners other than physicians may review services furnished by other practitioners in the same professional field.

(c) *DRG validation review.* Decisions about procedural and diagnostic information must be made by physicians. Technical coding issues must be reviewed by individuals with training and experience in ICD-9-CM coding.

(d) *Persons excluded from review.* (1) A person may not review health care services or make initial denial determinations or changes as a result of DRG validations if he or she, or a member of his or her family—

(i) Participated in developing or executing the beneficiary's treatment plan;

(ii) Is a member of the beneficiary's family; or

(iii) Is a governing body member, officer, partner, 5 percent or more owner, or managing employee in the health care facility where the services were or are to be furnished.

(2) A member of a reviewer's family is a spouse (other than a spouse who is legally separated under a decree of divorce or separate maintenance), child (including a legally adopted child), grandchild, parent, or grandparent.

§ 466.100 Use of norms and criteria.

(a) *Use of norms.* As specified in its contract, a PRO must use national, or where appropriate, regional norms in conducting review to achieve PRO contract objectives. However, with regard to determining the number of procedures selected for preadmission review, a PRO must use national admission norms.

(b) *Use of criteria.* In assessing the need for and appropriateness of an inpatient health care facility stay, a

PRO must apply criteria to determine—

(1) The necessity for facility admission and continued stay (in cases of day outliers in hospitals under prospective payment);

(2) The necessity for surgery and other invasive diagnostic and therapeutic procedures; or

(3) The appropriateness of providing services at a particular health care facility or at a particular level of care. The PRO must determine whether the beneficiary requires the level of care received or whether a lower and less costly level of care would be equally effective.

(c) *Establishment of criteria and standards.* For the conduct of review a PRO must—

(1) Establish written criteria based upon typical patterns of practice in the PRO area, or use national criteria where appropriate; and

(2) Establish written criteria and standards to be used in conducting quality review studies.

(d) *Variant criteria and standards.* A PRO may establish specific criteria and standards to be applied to certain locations and facilities in the PRO area if the PRO determines that—

(1) The patterns of practice in those locations and facilities are substantially different from patterns in the remainder of the PRO area; and

(2) There is a reasonable basis for the difference which makes the variation appropriate.

§ 466.102 Involvement of health care practitioners other than physicians.

(a) *Basic requirement.* Except as provided in paragraph (b) of this section, a PRO must meet the following requirements:

(1) Consult with the peers of the practitioners who furnish the services under review if the PRO reviews care and services delivered by health care practitioners other than physicians.

(2) Assure that in determinations regarding medical necessity of services or the quality of the services they furnish, these practitioners are involved in—

(i) Developing PRO criteria and standards;

(ii) Selecting norms to be used; and

(iii) Developing review mechanisms for care furnished by their peers.

(3) Ensure that an initial denial determination or a change as a result of DRG validation of services provided by a health care practitioner other than a physician is made by a physician only after consultation with a peer of that practitioner. Initial denial determinations and changes as a result of DRG validations must be made only by a physician or dentist.

(b) *Exception.* The requirements of paragraph (a) of this section do not apply if—

(1) The PRO has been unable to obtain a roster of peer practitioners available to perform review; or

(2) The practitioners are precluded from performing review because they participated in the treatment of the patient, the patient is a relative, or the practitioners have a financial interest in the health care facility as described in § 466.98(d).

(c) *Peer involvement in quality review studies.* Practitioners must be involved in the design of quality review studies, development of criteria, and actual conduct of studies involving their peers.

(d) *Consultation with practitioners other than physicians.* To the extent practicable, a PRO must consult with nurses and other professional health care practitioners (other than physicians defined in 1861(r) (1) and (2) of the Act) and with representatives of institutional and noninstitutional providers and suppliers with respect to the PRO's responsibility for review.

[50 FR 15330, Apr. 17, 1985; 50 FR 41886, Oct. 16, 1985]

§ 466.104 Coordination of activities.

In order to achieve efficient and economical review, a PRO must coordinate its activities (including information exchanges) with the activities of—

(a) Medicare fiscal intermediaries and carriers;

(b) Other PROs; and

(c) Other public or private review organizations as may be appropriate.

PART 473—RECONSIDERATIONS AND APPEALS

Subpart A—[Reserved]

Subpart B—Utilization and Quality Control Peer Review Organization (PRO) Reconsiderations and Appeals

Sec.

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Authority: Secs. 1102, 1154, 1155, 1866, 1871, and 1879 of the Social Security Act (42 U.S.C. 1302, 1320c-3, 1320c-4, 1395cc, 1395hh, and 1395pp).

Subpart A—[Reserved]

Subpart B—Utilization and Quality Control Peer Review Organization (PRO) Reconsiderations and Appeals

Source: 50 FR 15372, Apr. 17, 1985, unless otherwise noted.

§ 473.10 Scope.

This subpart establishes the requirements and procedures for—

(a) Reconsiderations conducted by a Utilization and Quality Control Peer Review Organization (PRO) or its subcontractor of initial denial determinations concerning services furnished or proposed to be furnished under Medicare;

(b) Hearings and judicial review of reconsidered determinations; and

(c) PRO review of a change in diagnostic and procedural coding information.

[50 FR 15372, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985]

§ 473.12 Statutory basis.

(a) Under section 1155 of the Act—

(1) A Medicare beneficiary, a provider, or an attending practitioner who is dissatisfied with a PRO initial denial determination made under the provisions of section 1154 of the Act, that services furnished or proposed to be furnished are not reasonable, necessary, or delivered in the most appropriate setting, is entitled to a reconsideration by the PRO that made the initial denial determination;

(2) A Medicare beneficiary is entitled to a hearing by an administrative law judge (ALJ) if $200 or more is still in controversy after a reconsidered determination; and

(3) A Medicare beneficiary is entitled to judicial review of a final determination of the Department if $2,000 or more is still in controversy.

(b) Under section 1866(a)(1)(F) of the Act, a hospital that is reimbursed by the Medicare program must maintain an agreement with a PRO under which the PRO will review the validity of diagnostic information furnished by the hospital.

§ 473.14 Applicability.

(a) *Basic provision.* This subpart applies to reconsiderations and hearings of a PRO initial denial determination involving the following issues:

(1) Reasonableness of services.

(2) Medical necessity of services.

(3) Appropriateness of the inpatient setting in which services were fur-

nished or are proposed to be furnished.

(b) *Concurrent appeal.* A reconsideration or hearing provided under this subpart fulfills the requirements of any other review, hearing, or appeal under the Act to which a party may be entitled with respect to the same issues.

(c) *Nonapplicability of rules to related determinations.* (1) A PRO may not reconsider its decision whether to grant grace days.

(2) Limitation of liability determinations on excluded coverage of certain services are made under section 1879 of the Act. Initial determinations under section 1879 and further appeals are governed by the reconsideration and appeal procedures in Part 405, Subpart G of this chapter for determinations under Medicare Part A, and Part 405, Subpart H of this chapter for determinations under Medicare Part B. References in those subparts to initial and reconsidered determinations made by an intermediary, carrier or HCFA should be read to mean initial and reconsidered determinations made by a PRO.

[50 FR 15372, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985]

§ 473.15 PRO review of changes resulting from DRG validation.

(a) *General rules.* (1) A provider or practitioner dissatisfied with a change to the diagnostic or procedural coding information made by a PRO as a result of DRG validation under section 1866(a)(1)(F) of the Act is entitled to a review of that change if—

(i) The change caused an assignment of a different DRG; and

(ii) Resulted in a lower payment.

(2) A beneficiary may obtain a review of a PRO DRG coding change only if that change results in noncoverage of a furnished service.

(3) The individual who reviews changes in DRG procedural or diagnostic information must be a physician, and the individual who reviews changes in DRG coding must be qualified through training and experience with ICD-9-CM coding.

(b) *Procedures.* Procedures described in §§ 473.18 through 473.36, and 473.48 (a) and (c) for a PRO reconsideration or reopening also apply to PRO review of a DRG coding change.

(c) *Finality of review.* No additional review or appeal for matters governed by paragraph (a) of this section is available.

[50 FR 15372, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985]

§ 473.16 Right to reconsideration.

A beneficiary, provider or practitioner who is dissatisfied with a PRO initial denial determination on one of the issues specified in § 473.14(a) has a right to a reconsideration of that determination by the PRO that made the initial denial determination.

§ 473.18 Location for submitting requests for reconsideration.

(a) *Beneficiaries.* Except as provided in paragraph (c) of this section concerning requests for expedited reconsideration, a beneficiary who wishes to obtain a reconsideration must submit a written request to one of the following:

(1) The PRO or the PRO subcontractor that made the initial determination.

(2) An SSA District Office.

(3) A Railroad Retirement Board Office, if the beneficiary is a railroad retiree.

(b) *Others.* A provider, physician or other practitioner that wishes to obtain reconsideration must submit a written request to the PRO or PRO subcontractor that made the initial determination.

(c) *Expedited reconsideration.* A request for an expedited reconsideration of a preadmission denial determination must be submitted directly to the PRO.

§ 473.20 Time limits for requesting reconsideration.

(a) *Basic rules.* (1) Except for a request for expedited reconsideration as provided in paragraph (c) of this section, or a late request with good cause under § 473.22, a dissatisfied party must file a request for reconsideration within 60 days after receipt of the notice of an initial determination.

(2) The date of receipt of the notice of the initial determination is pre-

sumed to be five days after the date on the notice, unless there is a reasonable showing to the contrary.

(3) A request is considered filed on the date it is postmarked.

(b) *Late filing of request.* A PRO will accept a request filed after 60 days after receipt of the notice of the initial determination if the PRO finds under the criteria set forth in § 473.22 that there was good cause for the party's failure to file a timely request.

(c) *Request for expedited reconsideration.* A request for an expedited reconsideration under § 473.18(c) must be submitted within three days after receipt of the notice of the initial denial determination.

§ 473.22 Good cause for late filing of a request for a reconsideration or hearing.

(a) *General Rule.* In determining whether a party has good cause for not filing a request for reconsideration or hearing timely, the PRO or ALJ, respectively, must consider the following:

(1) What circumstances kept the party from making the request on time.

(2) Whether an action by the PRO misled the party.

(3) Whether the party understood the requirements of the Act as affected by amendments to the Act, other legislation, or court decisions.

(b) *Examples.* Examples of circumstances in which good cause may exist include, but are not limited to, the following:

(1) A party was seriously ill and was prevented from requesting a reconsideration in person, through another person, or in writing.

(2) There was a death or serious illness in a party's immediate family.

(3) Important records were accidentally destoryed or damaged by fire or other cause.

(4) A party made a diligent effort but could not find or obtain necessary relevent information within the appropriate time period.

(5) A party requested additional information to further explain the determination within the time limit, and requested reconsideration within 60 days of receiving the explanation (or within 30 days for an Appeals Council hearing).

(6) The PRO gave the party incorrect or incomplete information about when and how to request a reconsideration or hearing.

(7) A party sent the request to another Government agency in good faith within the time limit, but the request did not reach an office authorized to receive the request until after the time period had expired.

(8) Other unusual or unavoidable circumstances exist that—

(i) Show that a party could not have known of the need to file timely; or

(ii) Prevented a party from filing timely.

§ 473.24 Opportunity for a party to obtain and submit information.

(a) Subject to the rules concerning disclosure of PRO information in section 1160 of the Act, at the request of a provider, practitioner or beneficiary, the PRO must provide an opportunity for examination of the material upon which the initial denial determination was based. The PRO may not furnish a provider, practitioner or beneficiary with—

(1) A record of the PRO deliberation; or

(2) The identity of the PRO review coordinators, physician advisors, or consultants who assisted in the initial denial determination without their consent.

(b) The PRO may require the requester to pay a reasonable fee for the reproduction of the material requested.

(c) The PRO must provide a party with an opportunity to submit new evidence before the reconsidered determination is made.

§ 473.26 Delegation of the reconsideration function.

A PRO may delegate the authority to reconsider an initial determination to a nonfacility subcontractor, including the organization that made the initial determination as a PRO subcontractor.

§ 473.28 Qualifications of a reconsideration reviewer.

A reconsideration reviewer must be someone who is—

(a) Qualified under § 466.98 of this chapter to make an initial determination.

(b) Not the individual who made the initial denial determination.

(c) A specialist in the type of services under review, except where meeting this requirement would compromise the effectiveness or efficiency of PRO review.

§ 473.30 Evidence to be considered by the reconsideration reviewer.

A reconsidered determination must be based on—

(a) The information that led to the initial determination;

(b) New information found in the medical records; or

(c) Additional evidence submitted by a party.

§ 473.32 Time limits for issuance of the reconsidered determination.

(a) *Beneficiaries.* If a beneficiary files a timely request for reconsideration of an initial denial determination, the PRO must complete its reconsidered determination and send written notice to the beneficiary within the following time limits—

(1) Within three working days after the PRO receives the request for reconsideration if—

(i) The beneficiary is still an inpatient in a hospital for the stay in question when the PRO receives the request for reconsideration; or

(ii) The initial determination relates to institutional services for which admission to the institution is sought, the initial determination was made before the patient was admitted to the institution; and a request was submitted timely for an expedited reconsideration.

(2) Within 10 working days after the PRO receives the request for reconsideration if the beneficiary is still an inpatient in a SNF for the stay in question when the PRO receives the request for reconsideration.

(3) Within 30 working days after the PRO receives the request for reconsideration if—

(i) The initial determination concerns ambulatory or noninstitutional services;

(ii) The beneficiary is no longer an inpatient in a hospital or SNF for the stay in question; or

(iii) The beneficiary does not submit a request for expedited reconsideration timely.

(b) *Providers or practitioners.* If the provider or practitioner files a request for reconsideration of an initial determination, the PRO must complete its reconsidered determination and send written notice to the provider or practitioner within 30 working days.

§ 473.34 Notice of a reconsidered determination.

(a) *Notice to parties.* A written notice of a PRO reconsidered determination must contain the following:

(1) The basis for the reconsidered determination.

(2) A detailed rationale for the reconsidered determination.

(3) A statement explaining the Medicare payment consequences of the reconsidered determination.

(4) A statement informing the parties of their appeal rights, including the information concerning what must be included in the request for hearing, the amount in controversy, locations for submitting a request for an administrative hearing and the time period for filing a request.

(b) *Notice to payers.* (1) A PRO must provide written notice of its reconsidered determination to the appropriate Medicare intermediary or carrier within 30 days if the initial determination is modified or reversed.

(2) This notice must contain adequate information to allow the intermediary or carrier to locate the claim file. This must include the name of the beneficiary, the Health Insurance Claim Number, the name of the provider, date of admission, and dates or services for which Medicare payment will not be made.

§ 473.36 Record of reconsideration.

(a) *PRO requirements.* A PRO must maintain the record of its reconsideration until the later of the following:

(1) Four years after the date on the notice of the PRO's reconsidered determination.

(2) Completion of litigation and the passage of the time period for filing all appeals.

(b) *Contents of the record.* The record of the reconsideration must include:

(1) The initial determination.

(2) The basis for the initial determination.

(3) Documentation of the date of the receipt of the request for reconsideration.

(4) The detailed basis for the reconsidered determination.

(5) Evidence submitted by the parties.

(6) A copy of the notice of the reconsidered determination that was provided to the parties.

(7) Documentation of the delivery or mailing and, if appropriate, the receipt of the notice of the reconsidered determination by the parties.

(c) *Confidentiality.* The record of a PRO reconsideration is subject to prohibitions against disclosure of information as specified in section 1160 of the Act.

§ 473.38 Finality of a reconsidered determination.

A PRO reconsidered determination is final and binding upon all parties to the reconsideration unless—

(a) A hearing is requested in accordance with § 473.40 and a final decision rendered; or

(b) The reconsidered determination is later reopened and revised in accordance with § 473.48.

[50 FR 15372, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985]

§ 473.40 Beneficiary's right to a hearing.

(a) *Amount in controversy.* If the amount in controversy is at least $200, a beneficiary (but not a provider or practitioner) who is dissatisfied with a PRO reconsidered determination may obtain a hearing by an administrative law judge (ALJ) of the Office of Hearings and Appeals of the SSA.

(b) *Subject matter.* A beneficiary has a right to a hearing on the following issues:

(1) Reasonableness of the services.

(2) Medical necessity of the services.

(3) Appropriateness of the setting in which the services were furnished.

(c) *Governing provisions.* The provisions of Subpart G, Reconsiderations and Appeals under the Hospital Insurance Program, of Part 405 of this chapter apply to hearings and appeals under this subpart unless they are inconsistent with specific provisions in this subpart. References in Subpart G to initial and reconsidered determinations made by an intermediary, carrier, or HCFA should be read to mean initial and reconsidered determinations made by a PRO.

[50 FR 15372, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985]

§ 473.42 Submitting a request for a hearing.

(a) *Where to submit the written request.* A beneficiary who wants to obtain a hearing under § 473.40 must submit a written request to one of the following:

(1) The office of the PRO or PRO subcontractor that made the initial determination.

(2) A SSA District Office.

(3) An office of the Office of Hearings and Appeals of SSA.

(4) An office of the Railroad Retirement Board, in the case of a beneficiary who is a railroad retiree.

(b) *Time limit for submitting a request for a hearing.* (1) The request for a hearing must be filed within 60 days of receipt of the notice of the PRO reconsidered determination, unless the time is extended for good cause as provided in § 473.22.

(2) The date of receipt of the notice of the reconsidered determination is presumed to be five days after the date on the notice, unless there is a reasonable showing to the contrary.

(3) A request is considered filed on the date it is postmarked.

§ 473.44 Determining the amount in controversy for a hearing.

(a) After a party has submitted a request for a hearing, the ALJ determines the amount in controversy in accordance with § 405.740 of this chapter.

(b) If the ALJ determines that the amount in controversy is less than $200, the ALJ, without holding a hearing, notifies the parties to the hearing that the parties have 15 calendar days to submit additional evidence to prove that the amount in controversy is at least $200.

(c) At the end of the 15-day period, if the ALJ determines that the amount in controversy is less than $200, the ALJ, without holding a hearing, dismisses the request for a hearing without ruling on the substantive issues involved in the appeal and notifies the parties to the hearing and the PRO that the PRO reconsidered determination is conclusive for Medicare payment purposes.

§ 473.46 Appeals Council and judicial review.

(a) The circumstances under which the Appeals Council of the Social Security Administration will review an ALJ hearing decision or dismissal are specified in 20 CFR 404.970, Cases the Appeals Council will review.

(b) If $2,000 or more is in controversy, a party may obtain judicial review of an Appeals Council decision, or an ALJ hearing decision if a request for review by the Appeals Council was denied, by filing a civil action under the Federal Rules of Civil Procedure within 60 days after the date the party received notice of the Appeals Council decision or denial.

§ 473.48 Reopening and revision of a reconsidered determination or a hearing decision.

(a) *PRO reopenings*—(*1*) *General rule*. A PRO or PRO subcontractor that made a reconsidered determination, or conducted a review of a DRG change as described in § 473.15, that is otherwise final, may reopen and revise the reconsidered determination or review, either on its own motion or at the request of a party, within one year from the date of the reconsidered determination or review.

(2) *Extension of time limit*. A PRO or PRO subcontractor may reopen and revise its reconsidered determination, or its review of a DRG change as described in § 473.15, that is otherwise final, after one year but within four years of the date of the determination or review if—

(i) The PRO receives new material evidence;

(ii) The PRO erred in interpretation or application of Medicare coverage policy;

(iii) There is an error apparent on the face of the evidence upon which the reconsidered determination was based; or

(iv) There is a clerical error in the statement of the reconsidered determination.

(b) *ALJ and Appeals Council Reopening—Applicable procedures*. The ALJ or the Appeals Council, whichever made the final decision, may reopen and revise the decision in accordance with the procedures set forth in § 405.750(b) of this chapter, which concerns reopenings and revisions under Subpart G of Part 405 of this chapter.

(c) *Fraud or similar abusive practice*. A reconsidered determination, a review of a DRG change, or a decision of an ALJ or the Appeals Council may be reopened and revised at any time, if the reconsidered determination, review, or decision was obtained through fraud or a similar abusive practice that does not support a formal finding of fraud.

PART 476—ACQUISITION, PROTECTION, AND DISCLOSURE OF PEER REVIEW INFORMATION

Subpart A—[Reserved]

Subpart B—Utilization and Quality Control Peer Review Organizations (PROs)

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AUTHORITY: Secs. 1102, 1154(a), 1156(a), and 1160 of the Social Security Act (42 U.S.C. 1302, 1320c-3(a), 1320c-5(a), and 1320c-9).

Subpart A—[Reserved]

Subpart B—Utilization and Quality Control Peer Review Organizations (PROs)

SOURCE: 50 FR 15359, Apr. 17, 1985, unless otherwise noted.

GENERAL PROVISIONS

§ 476.101 Scope and definitions.

(a) *Scope.* This subpart sets forth the policies and procedures governing—

(1) Disclosure of information collected, acquired or generated by a Utilization and Quality Control Peer Review Organization (PRO) (or the review component of a PRO subcontractor) in performance of its responsibilities under the Act and these regulations; and

(2) Acquisition and maintenance of information by a PRO to comply with its responsibilities under the Act.

(b) *Definitions.* As used in this part:

Abuse means any unlawful conduct relating to items or services for which payment is sought under Title XVIII of the Act.

Aggregate statistical data means any utilization, admission, discharge or diagnostic related group (DRG) data arrayed on a geographic, institutional or other basis in which the volume and frequency of services are shown without identifying any individual.

Confidential information means any of the following:

(1) Information that explicitly or implicitly identifies an individual patient, practitioner or reviewer.

(2) Sanction reports and recommendations.

(3) Quality review studies which identify patients, practitioners or institutions.

(4) PRO deliberations.

Health care facility or *facility* means an organization involved in the delivery of health care services or items for which reimbursement may be made in whole or in part under Title XVIII of the Act.

Implicitly identify(ies) means data so unique or numbers so small so that identification of an individual patient, practitioners or reviewer would be obvious.

Non-facility organization means a corporate entity that: (1) Is not a health care facility; (2) is not a 5 percent or more owner of a facility; and (3) is not owned by one or more health care facilities in the PRO area.

Patient representative means—(1) an individual designated by the patient, in writing, as authorized to request and receive PRO information that would otherwise be disclosable to that patient; or (2) an individual identified by the PRO in accordance with § 476.132(c)(3) when the beneficiary is mentally, physically or legally unable to designate a representative.

Practitioner means an individual credentialed within a recognized health care discipline and involved in providing the services of that discipline to patients.

PRO deliberations means discussions or communications (within a PRO or between a PRO and a PRO subcontractor) including, but not limited to, review notes, minutes of meetings and any other records of discussions and judgments involving review matters regarding PRO review responsibilities and appeals from PRO determinations, in which the opinions of, or judgment about, a particular individual or institution can be discerned.

PRO information means any data or information collected, acquired or generated by a PRO in the exercise of its duties and functions under Title XI Part B or Title XVIII of the Act.

PRO interpretations and generalizations on the quality of health care means an assessment of the quality of care furnished by an individual provider or group of providers based on the PRO's knowledge of the area gained from its medical review experience (e.g., quality review studies) and any other information obtained through the PRO's review activities.

PRO review system means the PRO and those organizations and individuals who either assist the PRO or are directly responsible for providing medical care or for making determinations with respect to the medical necessity, appropriate level and quality of health care services that may be reimbursed under the Act. The system includes—

(1) The PRO and its officers, members and employees;

(2) PRO subcontractors;

(3) Health care institutions and practitioners whose services are reviewed;

(4) PRO reviewers and supporting staff; and

(5) Data support organizations.

Public information means information which has been disclosed to the public.

Quality review study means an assessment, conducted by or for a PRO, of a patient care problem for the purpose of improving patient care through peer analysis, intervention, resolution of the problem and follow-up.

Quality review study information means all documentation related to the quality review study process.

Reviewer means review coordinator, physician, or other person authorized to perform PRO review functions.

Sanction report means a report filed pursuant to section 1156 of the Act and Part 474 of this chapter documenting the PRO's determination that a practitioner or institution has failed to meet obligations imposed by section 1156 of the Act.

Shared health data system means an agency or other entity authorized by Federal or State law that is used by the PRO review system to provide information or to conduct or arrange for the collection, processing, and dissemination of information on health care services.

Subcontractor means a facility or a non-facility organization under contract with a PRO to perform PRO review functions.

[50 FR 15359, Apr. 17, 1985; 50 FR 41886, Oct. 16, 1985]

§ 476.102 Statutory bases for acquisition and maintenance of information.

(a) Section 1154(a)(7)(C) of the Act requires PROs to the extent necessary and appropriate to examine the pertinent records of any practitioner or provider of health care services for which payment may be made under Title XVIII of the Act.

(b) Section 1154(a)(9) of the Act requires PROs to collect and maintain information necessary to carry out their responsibilities under the Act.

(c) Section 1156(a)(3) of the Act requires health care practitioners and providers to maintain evidence of the medical necessity and quality of health care services they provide to Medicare patients as required by PROs.

§ 476.103 Statutory bases for disclosure of information.

(a) Section 1154(a)(10) of the Act requires PROs to exchange information with intermediaries and carriers with contracts under sections 1816 and 1842 of the Act, other PROs, and other public or private review organizations as appropriate.

(b) Section 1160 of the Act provides that PRO information must be held in confidence and not be disclosed except where—

(1) Necessary to carry out the purpose of Title XI Part B of the Act;

(2) Specifically permitted or required under this subpart;

(3) Necessary, and in the manner prescribed under this subpart, to assist Federal and State agencies recognized by the Secretary as having responsibility for identifying and investigating cases or patterns of fraud or abuse;

(4) Necessary, and in the manner prescribed under the subpart to assist Federal or State agencies recognized by the Secretary as having responsibility for identifying cases or patterns involving risks to the public health;

(5) Necessary, and in the manner prescribed under this subpart, to assist appropriate State agencies having responsibility for licensing or certification of providers or practitioners; or

(6) Necessary, and in the manner prescribed under this subpart to assist Federal or State health planning agencies by furnishing them aggregate statistical data on a geographical, institutional or other basis.

[50 FR 15359, Apr. 17, 1985; 50 FR 41886, Oct. 16, 1985]

§ 476.104 Procedures for disclosure by a PRO.

(a) *Notice to accompany disclosure.*

(1) Any disclosure of information under the authority of this subpart is subject to the requirements in § 476.105 relating to the providing of a notice of the disclosure.

(2) Disclosure of confidential information made under the authority of this subpart, except as provided in § 476.106, must be accompanied by a written statement informing the recipient that the information may not be redisclosed except as provided under § 476.107 that limits redisclosure.

(b) *PRO interpretations.* A PRO may provide a statement of comment, analysis, or interpretation to guide the recipient in using information disclosed under this subpart.

(c) *Fees.* A PRO may charge a fee to cover the cost of providing information authorized under this subpart. These fees may not exceed the amount necessary to recover the cost to the PRO for providing the information.

(d) *Format for disclosure of public information.* A PRO is required to disclose public information (§ 476.120(a)(6)) only in the form in which it is acquired by the PRO or in the form in which it is maintained for PRO use.

(e) *Medicare provider number.* A PRO must include the provider identification number assigned by the Medicare program on information that HCFA requests.

§ 476.105 Notice of disclosures made by a PRO.

(a) *Notification of the disclosure of nonconfidential information.* Except as permitted under § 476.106, at least 30 calender days before disclosure of nonconfidential information, the PRO must notify an identified institution of its intent to disclose information about the institution (other than reports routinely submitted to HCFA or Medicare fiscal intermediaries, or to or from PRO subcontractors, or to or from the institution) and provide the institution with a copy of the information. The institution may submit comments to the PRO that must be attached to the information disclosed if received before disclosure, or forwarded separately if received after disclosure.

(b) *Notification of the disclosure of confidential information.* (1) A PRO must notify the practitioner who has treated a patient, of a request for disclosure to the patient or patient representative in accordance with the requirements and exceptions to the requirements for disclosure specified under § 476.132.

(2) A PRO must notify a practitioner or institution of the PRO's intent to disclose information on the practitioner or institution to an investigative or licensing agency (§§ 476.137 and 476.138) except for cases specified in § 476.106 involving fraud or abuse or imminent danger to individuals or the public health. The practitioner or institution must be notified and provided a copy of the information to be disclosed at least 30 calendar days before the PRO discloses the identifying information. The PRO must forward with the information any comments submitted by the practitioner or institution in response to the PRO notice if received before disclosure, or forwarded separately if received after disclosure.

[50 FR 15359, Apr. 17, 1985; 50 FR 41886, Oct. 16, 1985]

§ 476.106 Exceptions to PRO notice requirements.

(a) *Imminent danger to individuals or public health.* When the PRO determines that requested information is necessary to protect against an imminent danger to individuals or the public health, the notification required in § 476.105 may be sent simultaneously with the disclosure.

(b) *Fraud or Abuse.* The notification requirement in § 476.105 does not apply if—

(1) The disclosure is made in an investigation of fraud or abuse by the Office of the Inspector General or the General Accounting Office; or

(2) The disclosure is made in an investigation of fraud or abuse by any other Federal or State fraud or abuse agency and the investigative agency specifies in writing that the information is related to a potentially prosecutable criminal offense.

§ 476.107 Limitations on redisclosure.

Persons or organizations that obtain confidential PRO information must not further disclose the information to any other person or organization except—

(a) As directed by the PRO to carry out a disclosure permitted or required under a particular provision of this part;

(b) As directed by HCFA to carry out specific responsibilities of the Secretary under the Act;

(c) As necessary for HCFA to carry out its responsibilities for appeals under section 1155 of the Act or for HCFA to process sanctions under section 1156 of the Act;

(d) If the health care services furnished to an individual patient are reimbursed from more than one source, these sources of reimbursement may exchange confidential information as necessary for the payment of claims;

(e) If the information is acquired by the PRO from another source and the receiver of the information is authorized under its own authorities to acquire the information directly from the source, the receiver may disclose the information in accordance with the source's redisclosure rules;

(f) As necessary for the General Accounting Office to carry out its statutory responsibilities;

(g) Information pertaining to a patient or practitioner may be disclosed by that individual provided it does not identify any other patient or practitioner;

(h) An institution may disclose information pertaining to itself provided it does not identify an individual patient or practitioner;

(i) Governmental fraud or abuse agencies and State licensing or certification agencies recognized by HCFA may disclose information as necessary in a judicial, administrative or other formal legal proceeding resulting from an investigation conducted by the agency;

(j) State and local public health officials to carry out their responsibilities, as necessary, to protect against a substantial risk to the public health; or

(k) As necessary for the Office of the Inspector General to carry out its statutory responsibilities.

[50 FR 15359, Apr. 17, 1985; 50 FR 41886, Oct. 16, 1985]

§ 476.108 Penalties for unauthorized disclosure.

A person who discloses information not authorized under Title XI Part B of the Act or the regulations of this part will, upon conviction, be fined no more than $1,000, or be imprisoned for no more than six months, or both, and will pay the costs of prosecution.

§ 476.109 Applicability of other statutes and regulations.

The provisions of 42 U.S.C. 290dd-3 and 290ee-3 governing confidentiality of alcohol and drug abuse patients' records, and the implementing regulations at 42 CFR Part 2, are applicable to PRO information.

[50 FR 15359, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985]

PRO Access to Information

§ 476.111 PRO access to records and information of institutions and practitioners.

(a) A PRO is authorized to have access to and obtain records and information pertinent to the health care services furnished to Medicare patients, held by any institution or practitioner in the PRO area. The PRO may require the institution or practitioner to provide copies of such records or information to the PRO.

(b) A PRO may obtain non-Medicare patient records relating to review performed under a non-Medicare PRO contract if authorized by those patients in accordance with State law.

(c) In accordance with its quality review responsibilities under the Act, a PRO may have access to and obtain information from, the records of non-Medicare patients if authorized by the institution or practitioner.

[50 FR 15359, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985]

§ 476.112 PRO access to records and information of intermediaries and carriers.

A PRO is authorized to have access to and require copies of Medicare records or information held by intermediaries or carriers if the PRO determines that the records or information are necessary to carry out PRO review responsibilities.

§ 476.113 PRO access to information collected for PRO purposes.

(a) Institutions and other entities must disclose to the PRO information collected by them for PRO purposes.

(b) Information collected or generated by institutions or practitioners to carry out quality review studies must be disclosed to the PRO.

§ 476.114 Limitation on data collection.

A PRO or any agent, organization, or institution acting on its behalf, that is collecting information under authority of this part, must collect only that information which is necessary to accomplish the purposes of Title XI Part B of the Act in accordance with 44 U.S.C. Chapter 35, Coordination of Federal Reporting Services Information Policy.

PRO Responsibilities

§ 476.115 Requirements for maintaining confidentiality.

(a) *Responsibilities of PRO officers and employees.* The PRO must provide reasonable physical security measures to prevent unauthorized access to PRO information and to ensure the integrity of the information, including those measures needed to secure computer files. Each PRO must instruct its officers and employees and health care institution employees participating in PRO activities of their responsibility to maintain the confidentiality of information and of the legal penalties that may be imposed for unauthorized disclosure of PRO information.

(b) *Responsible individuals within the PRO.* The PRO must assign a single individual the responsibility for maintaining the system for assuring the confidentiality of information within the PRO review system. That individual must notify HCFA of any violations of these regulations.

(c) *Training requirements.* The PRO must train participants of the PRO review system in the proper handling of confidential information.

(d) *Authorized access.* An individual participating in the PRO review system on a routine or ongoing basis must not have authorized access to confidential PRO information unless that individual—

(1) Has completed a training program in the handling of PRO information in accordance with paragraph (c) of this section or has received comparable training from another source; and

(2) Has signed a statement indicating that he or she is aware of the legal penalties for unauthorized disclosure.

(e) *Purging of personal identifiers.* (1) The PRO must purge or arrange for purging computerized information, patient records and other noncomputerized files of all personal identifiers as soon as it is determined by HCFA that those identifiers are no longer necessary.

(2) The PRO must destroy or return to the facility from which it was collected confidential information generated from computerized information, patient records and other noncomputerized files when the PRO determines that the maintenance of hard copy is no longer necessary to serve the specific purpose for which it was obtained or generated.

(f) *Data system procedures.* The PRO must assure that organizations and consultants providing data services to the PRO have established procedures for maintaining the confidentiality of PRO information in accordance with requirements defined by the PRO and consistent with procedures established under this part.

§ 476.116 Notice to individuals and institutions under review.

The PRO must establish and implement procedures to provide patients, practitioners, and institutions under review with the following information—

(a) The title and address of the person responsible for maintenance of PRO information;

(b) The types of information that will be collected and maintained;

(c) The general rules governing disclosure of PRO information; and

(d) The procedures whereby patients, practitioners, and institutions may obtain access to information about themselves.

DISCLOSURE OF NONCONFIDENTIAL INFORMATION

§ 476.120 Information subject to disclosure.

Subject to the procedures for disclosure and notice of disclosure specified in §§ 476.104 and 476.105, the PRO must disclose—

(a) Nonconfidential information to any person upon request, including—

(1) The norms, criteria, and standards it uses for initial screening of cases, and for other review activities;

(2) Winning technical proposals for contracts from the Department, and winning technical proposals for subcontracts under those contracts (except for proprietary or business information);

(3) Copies of documents describing administrative procedures, agreed to between the PRO and institutions or between a PRO and the Medicare intermediary or Medicare carrier;

(4) Routine reports submitted by the PRO to HCFA to the extent that they do not contain confidential information.

(5) Summaries of the proceedings of PRO regular and other meetings of the governing body and general membership except for those portions of the summaries involving PRO deliberations, which are confidential information and subject to the provisions of § 476.139;

(6) Public information in its possession;

(7) Aggregate statiscal information that does not implicitly or explicitly identify individual patients, practitioners or reviewers;

(8) Quality review study information including summaries and conclusions from which the identification of patients, practitioners and institutions has been deleted; and

(9) Information describing the characteristics of a quality review study, including a study design and methodology.

(b) Aggregate statistical information that does not implicitly or explicitly identify individual patients, practitioners or reviewers, to Federal or State health planning agencies (including Health Systems Agencies and State Health Planning and Development Agencies) in carrying out their health care planning and related activities.

[50 FR 15359, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985]

§ 476.121 Optional disclosure of nonconfidential information.

A PRO may, on its own initiative, subject to the notification requirements in § 476.105, furnish the information available under § 476.120 to any person, agency, or organization.

DISCLOSURE OF CONFIDENTIAL INFORMATION

§ 476.130 Disclosure to the Department.

Except as limited by §§ 476.139(a) and 476.140 of this subpart, PROs must disclose all information requested by the Department to it in the manner and form required.

§ 476.131 Access to medical records for the monitoring of PROs.

HCFA or any person, organization or agency authorized by the Department or Federal statute to monitor a PRO will have access to medical records maintained by institutions or health care practitioners on Medicare patients. The monitor can require copies of the records.

§ 476.132 Disclosure of information about patients.

(a) *General requirements for disclosure.* Except as specified in paragraph (b) of this section, a PRO must—

(1) Disclose patient identified information in its possession to the identified patient or the patient's representative if—

(i) The patient or the patient's representative requests the information in writing;

(ii) The request by a patient's representative includes the designation, by the patient, of the representative; and

(iii) All other patient and practitioner identifiers have been removed.

(2) Seek the advice of the attending practitioner that treated the patient regarding the appropriateness of direct disclosure to the patient 15 days before the PRO provides the requested information. If the attending practitioner states that the released information could harm the patient, the PRO must act in accordance with paragraph (c)(2) of this section. The PRO must make disclosure to the patient or patient's representative within 30 calendar days of receipt of the request.

(b) *Exceptions.* (1) If the request is in connection with an initial denial determination under section 1154(a)(3) of the Act, the PRO—

(i) Need not seek the advice of the practitioner that treated the patient regarding the appropriateness of direct disclosure to the patient; and

(ii) Must provide only the information used to support that determination in accordance with the procedures for disclosure of information relating to determinations under § 473.24.

(2) A PRO must disclose information regarding PRO deliberations only as specified in § 476.139(a).

(3) A PRO must disclose quality review study information only as specified in § 476.140.

(c) *Manner of disclosure.* (1) The PRO must disclose the patient information directly to the patient unless knowledge of the information could harm the patient.

(2) If knowledge of the information could harm the patient, the PRO must disclose the information to the patient's designated representative.

(3) If the patient is mentally, physically or legally unable to designate a representative, the PRO must disclose the information to a person whom the PRO determines is responsible for the patient.

The PRO must first attempt to make that determination based on the medical record. If the responsible person is not named in the medical record, then the PRO may rely on the attending practitioner for the information. If the practitioner is unable to provide a name, then the PRO must make a determination based on other reliable information.

[50 FR 15359, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985]

§ 476.133 Disclosure of information about practitioners, reviewers and institutions.

(a) *General requirements for disclosure.* Except as specified in paragraph (b) of this section, the following provisions are required of the PRO.

(1) *Disclosure to the identified individual or institution.* A PRO must disclose, to particular practitioners, reviewers and institutions, information about themselves, upon request, and may disclose it to them without a request.

(2) *Disclosure to others.* (i) A PRO must disclose to an institution, upon request, information on a practitioner to the extent that the information displays practice or performance patterns of the practitioner in that institution.

(ii) In accordance with section 1160 of the Act, a PRO must disclose information that displays practice or performance patterns of a practitioner or institution in accordance with the procedures for disclosures specified in §§ 476.137 and 476.138 to—

(A) Federal and State agencies that are responsible for the investigation of fraud and abuse of the Medicare or Medicaid programs, and

(B) Federal and State agencies that are responsible for licensing and certification of practitioners and providers.

(iii) A PRO may disclose to any person, agency or organization, information on a particular practitioner or reviewer with the consent of that practitioner or reviewer provided that the information does not identify other individuals.

(b) *Exceptions.* (1) If the request is in connection with an initial denial determination or a change resulting from a diagnostic related group (DRG) coding validation under Part 466 of this subchapter, the PRO must provide only the information used to support that determination in accordance with the procedures for disclosure of information relating to determinations under § 473.24.

(2) A PRO must disclose information regarding PRO deliberations only as specified in § 476.139(a).

(3) A PRO must disclose quality review study information only as specified in § 476.140.

[50 FR 15359, Apr. 17, 1885, as amended at 52 FR 37458, Oct. 7, 1987; 52 FR 47004, Dec. 11, 1987]

§ 476.134 Verification and amendment of PRO information.

(a) A PRO must verify the accuracy of its information concerning patients, practitioners, reviewers, and institutions and must permit the individual or institution to request an amendment of pertinent information that is in the possession of the PRO.

(b) If the PRO agrees with the request for amendment, the PRO must correct the information in its possession. If the information being amended has already been disclosed, the PRO must forward the amended information to the requester where it may affect decisions about a particular provider, practitioner or case under review.

(c) If the PRO disagrees with the request for amendment, a notation of the request, reasons for the request, and the reasons for refusal must be included with the information and attached to any disclosure of the information.

[50 FR 15358, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985]

§ 476.135 Disclosure necessary to perform review responsibilities.

(a) *Disclosure to conduct review.* The PRO must disclose or arrange for disclosure of information to individuals and institutions within the PRO review system as necessary to fulfill their particular duties and functions under Title XI Part B of the Act.

(b) *Disclosure to consultants and subcontractors.* The PRO must disclose to consultants or subcontractors the information they need to provide specified services to the PRO.

(c) *Disclosure to other PRO and medical review boards.* The PRO must disclose—

(1) To another PRO, information on patients and practitioners who are subject to review by the other PRO; and

(2) To medical review boards established under section 1881 of the Act, confidential information on patients, practitioners and institutions receiving

or furnishing end stage renal disease services.

§ 476.136 Disclosure to intermediaries and carriers.

(a) *Required disclosure.* Except as specified in §§ 476.139(a) and 476.140 relating to disclosure of PRO deliberations and quality review study information, a PRO must disclose to intermediaries and carriers PRO information that relates to, or is necessary for, payment of claims for Medicare as follows:

(1) Review determinations and claims forms for health care services, furnished in the manner and form agreed to by the PRO and the intermediary or carrier.

(2) Upon request, copies of medical records acquired from practitioners or institutions for review purposes.

(3) PRO information about a particular patient or practitioner if the PRO and the intermediary or carrier (or HCFA if the PRO and the intermediary or carrier cannot agree) determine that the information is necessary for the administration of the Medicare program.

(b) *Optional disclosure.* The PRO may disclose the information specified in paragraph (a) of this section to intermediaries and carriers without a request.

§ 476.137 Disclosure to Federal and State enforcement agencies responsible for the investigation or identification of fraud or abuse of the Medicare or Medicaid programs.

(a) *Required disclosure.* Except as specified in §§ 476.139(a) and 476.140 relating to disclosure of PRO deliberations and quality review study information, the PRO must disclose confidential information relevant to an investigation of fraud or abuse of the Medicare or medicaid programs, including PRO medical necessity determinations and other information that includes patterns of the practice or performance of a practitioner or institution, when a written request is received from a State or Federal enforcement agency responsible for the investigation or identification of fraud or abuse of the Medicare or Medicaid programs that—

(1) Identifies the name and title of the individual initiating the request,

(2) Identifies the physician or institution about which information is requested, and

(3) States affirmatively that the institution or practitioner is currently under investigation for fraud or abuse of the Medicare or Medicaid programs and that the information is needed in furtherance of that investigation.

(b) *Optional disclosure.* The PRO may provide the information specified in paragraph (a) of this section to Federal or State fraud and abuse enforcement agencies responsible for the investigation or identification of fraud or abuse of the Medicare or Medicaid programs, without a request.

[50 FR 15358, Apr. 17, 1985, as amended at 52 FR 37458, Oct. 7, 1987]

§ 476.138 Disclosure for other specified purposes.

(a) *General requirements for disclosure.* Except as specified in paragraph (b) of this section, the following provisions are required of the PRO.

(1) *Disclosure to licensing and certification bodies.* (i) A PRO must disclose confidential information upon request, to State or Federal licensing bodies responsible for the professional licensure of a practitioner or a particular institution. Confidential information, including PRO medical necessity determinations that display the practice or performance patterns of that practitioner, must be disclosed by the PRO but only to the extent that it is required by the agency to carry out a function within the jurisdiction of the agency under Federal or State law.

(ii) A PRO may provide the information specified in paragraph (a)(1)(i) of this section to the State or Federal licensing body without request.

(2) *Disclosure to State and local public health officials.* A PRO must disclose PRO information to State and local public health officials whenever the PRO determines that the disclosure of the information is necessary to protect against a substantial risk to the public health.

(3) *Disclosure to the courts.* Patient identified records in the possession of a PRO are not subject to subpoena or

discovery in a civil action, including an administrative, judicial or arbitration proceeding.

(b) *Exceptions.* (1) The restriction set forth in paragraph (a)(3) of this section does not apply to HHS, including Inspector General, administrative subpoenas issued in the course of audits and investigations of Department programs, in the course of administrative hearings held under the Social Security Act or to disclosures to the General Accounting Office as necessary to carry out its statutory responsibilities.

(2) A PRO must disclose information regarding PRO deliberations and quality review study information only as specified in §§ 476.139(a) and 476.140.

[50 FR 15359, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985]

§ 476.139 Disclosure of PRO deliberations and decisions.

(a) *PRO deliberations.* (1) A PRO must not disclose its deliberations except to—

(i) HCFA, at the PRO office or at a subcontracted organization;

(ii) HCFA, to the extent that the deliberations are incorporated in sanction and appeals reports; or

(iii) The Office of the Inspector General, and the General Accounting Office as necessary to carry out statutory responsibilities.

(2) PRO deliberations are not disclosable, either in written form or through oral testimony, in connection with the administrative hearing or review of a beneficiary's claim.

(b) *Reasons for PRO decisions.* (1) A PRO may disclose to those who have access to PRO information under other provisions of this subpart, the reasons for PRO decisions pertaining to that information provided that the opinions or judgements of a particular individual or practitioner cannot be identified.

(2) A PRO must disclose, if requested in connection with the administrative hearing or review of a beneficiary's claim, the reasons for PRO decisions. The PRO must include the detailed facts, findings and conclusions supporting the PRO's determination. The PRO must insure that the opinions or judgements of a particular individual or practitioner cannot be identified through the materials that are disclosed.

§ 476.140 Disclosure of quality review study information.

(a) A PRO must disclose, onsite, quality review study information with identifiers of patients, practitioners or institutions to—

(1) Representatives of authorized licensure, accreditation or certification agencies as is required by the agencies in carrying out functions which are within the jurisdiction of such agencies under state law; to federal and state agencies responsible for identifying risks to the public health when there is substantial risk to the public health; HCFA; or to Federal and State fraud and abuse enforcement agencies;

(2) An institution or practitioner, if the information is limited to health care services furnished by the institution or practitioner; and

(3) A medical review board established under section 1881 of the Act pertaining to end-stage renal disease facilities, if the information is limited to health care services subject to its review.

(b) A PRO must disclose quality review study information with identifiers of patients, practitioners or institutions to the Office of the Inspector General and the General Accounting Office as necessary to carry out statutory responsibilities.

(c) A PRO may disclose information offsite from a particular quality review study to any institution or practitioner involved in that study, provided the disclosed information is limited to that institution or practitioner.

(d) An institution or group of practitioners may redisclose quality review study information, if the information is limited to health care services they provided.

(e) Quality review study information with patient identifiers is not subject to subpoena or discovery in a civil action, including an administrative, judicial or arbitration proceeding. This restriction does not apply to HHS, including Inspector General, administrative subpoenas issued in the course of audits and investigations of Department programs, in the course of administrative hearings held under the Social Security Act, or to disclosures to the General Accounting Office as necessary to carry out its statutory responsibilities.

§ 476.141 Disclosure of PRO interpretations on the quality of health care.

Subject to the procedures for disclosure and notice of disclosure specified in §§ 476.104 and 476.105, a PRO may disclose to the public PRO interpretations and generalizations on the quality of health care that identify a particular institution.

§ 476.142 Disclosure of sanction reports.

(a) The PRO must disclose sanction reports directly to the Office of the Inspector General and, if requested, to HCFA.

(b) The PRO must upon request, and may without a request, disclose sanction reports to State and Federal agencies responsible for the identification, investigation or prosecution of cases of fraud or abuse in accordance with § 476.137.

(c) HCFA will disclose sanction determinations in accordance with Part 474 of this chapter.

§ 476.143 PRO involvement in shared health data systems.

(a) *Information collected by a PRO.* Except as prohibited in paragraph (b) of this section, information collected by a PRO may be processed and stored by a cooperative health statistics system established under the Public Health Service Act (42 U.S.C. 242k) or other State or Federally authorized shared data system.

(b) *PRO participation.* A PRO may not participate in a cooperative health statistics system or other shared health data system if the disclosure rules of the system would prevent the PRO from complying with the rules of this part.

(c) *Disclosure of PRO information obtained by a shared health data system.* PRO information must not be disclosed by the shared health data system unless—

(1) The source from which the PRO acquired the information consents to or requests disclosure; or

(2) The PRO requests the disclosure of the information to carry out a disclosure permitted under a provision of this part.

SUBCHAPTER E—STANDARDS AND CERTIFICATION

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

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AUTHORITY: Secs. 1102, 1138, 1814(a)(6), 1861 (e), (f), (k), (r), (v)(1)(G), (z), and (ee), 1864, 1871, 1883, 1886, 1902(a)(30), and 1905(a) of the Social Security Act (42 U.S.C. 1302, 1338, 1395f(a)(6), 1395x (e), (f), (k), (r), (v)(1)(G), (z), and (ee), 1395aa, 1395hh, 1395tt, 1395ww, 1396a(a)(30), and 1396(a)).

SOURCE: 51 FR 22042, June 17, 1986, unless otherwise noted.

Subpart A—General Provisions

§ 482.1 Basis and scope.

(a) *Basis in legislation.* (1) Section 1861(e) of the Act provides that—

(i) Hospitals participating in Medicare must meet certain specified requirements; and

(ii) The Secretary may impose additional requirements if they are found necessary in the interest of the health and safety of the individuals who are furnished services in hospitals.

(2) Section 1861(f) of the Act provides that an institution participating in Medicare as a psychiatric hospital must meet certain specified requirements imposed on hospitals under section 1861(e), must be primarily engaged in providing, by or under the supervision of a physician, psychiatric services for the diagnosis and treatment of mentally ill persons, must maintain clinical records and other records that the Secretary finds necessary, and must meet staffing requirements that the Secretary finds necessary to carry out an active program of treatment for individuals who are furnished services in the hospital. A distinct part of an institution can participate as a psychiatric hospital if the in-

stitution meets the specified 1861(e) requirements and is primarily engaged in providing psychiatric services, and if the distinct part meets the records and staffing requirements that the Secretary finds necessary.

(3) Section 1905(a) of the Act provides that "medical assistance" (Medicaid) payments may be applied to various hospital services. Regulations interpreting those provisions specify that hospitals receiving payment under Medicaid must meet the requirements for participation in Medicare (except in the case of medical supervision of nurse-midwife services. See §§440.10 and 440.165 of this chpater.).

(b) *Scope.* Except as provided in Subpart S of Part 405 of this chapter, the provisions of this part serve as the basis of survey activities for the purpose of determining whether a hospital qualifies for a provider agreement under Medicare and Medicaid.

§ 482.2 Provision of emergency services by nonparticipating hospitals.

(a) The services of an institution that does not have an agreement to participate in the Medicare program may, nevertheless, be reimbursed under the program if—

(1) The services are emergency services; and

(2) The institution meets the requirements of section 1861(e) (1) through (5) and (7) of the Act. Rules applicable to emergency services furnished by nonparticipating hospitals are set forth in Subpart G of Part 424 of this chapter.

(b) Secton 440.170(e) of this chapter defines emergency hospital services for purposes of Medicaid reimbursement.

[51 FR 22042, June 17, 1986, as amended at 53 FR 6648, Mar. 2, 1988]

Subpart B—Administration

§ 482.11 Condition of participation: Compliance with Federal, State and local laws.

(a) The hospital must be in compliance with applicable Federal laws related to the health and safety of patients.

(b) The hospital must be—

(1) Licensed; or

(2) Approved as meeting standards for licensing established by the agency of the State or locality responsible for licensing hospitals.

(c) The hospital must assure that personnel are licensed or meet other applicable standards that are required by State or local laws.

§ 482.12 Condition of participation: Governing body.

The hospital must have an effective governing body legally responsible for the conduct of the hospital as an institution. However, if a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this Part that pertain to the governing body.

(a) *Standard: Medical staff.* The governing body must:

(1) Determine, in accordance with State law, which categories of practitioners are eligible candidates for appointment to the medical staff;

(2) Appoint members of the medical staff after considering the recommendations of the existing members of the medical staff;

(3) Assure that the medical staff has bylaws;

(4) Approve medical staff bylaws and other medical staff rules and regulations;

(5) Ensure that the medical staff is accountable to the governing body for the quality of care provided to patients;

(6) Ensure the criteria for selection are individual character, competence, training, experience, and judgment; and

(7) Ensure that under no circumstances is the accordance of staff membership or professional privileges in the hospital dependent solely upon certification, fellowship, or membership in a specialty body or society.

(b) *Standard: Chief executive officer.* The governing body must appoint a chief executive officer who is responsible for managing the hospital.

(c) *Standard: Care of patients.* In accordance with hospital policy, the governing body must ensure that the following requirements are met:

(1) Every patient is under the care of:

(i) A doctor of medicine or osteopathy (This provision is not to be construed to limit the authority of a doctor of medicine or osteopathy to delegate tasks to other qualified health care personnel to the extent recognized under State law or a State's regulatory mechanism.);

(ii) A doctor of dental surgery or dental medicine who is legally authorized to practice dentistry by the State and who is acting within the scope of his or her license;

(iii) A doctor of podiatric medicine, but only with respect to functions which he or she is legally authorized by the State to perform;

(iv) A doctor of optometry who is legally authorized to practice optometry by the State, but only with respect to services related to the condition of aphakia; or

(v) A chiropractor who is licensed by the State or legally authorized to perform the services of a chiropractor, but only with respect to treatment by means of manual manipulation of the spine to correct a subluxation demonstrated by x-ray to exist.

(2) Patients are admitted to the hospital only on the recommendation of a licensed practitioner permitted by the State to admit patients to a hospital. If a patient is admitted by a practitioner not specified in paragraph (c)(1) of this section, the patient is under the care of a doctor of medicine or osteopathy.

(3) A doctor of medicine or osteopathy is on duty or on call at all times.

(4) A doctor of medicine or osteopathy is responsible for the care of each patient with respect to any medical or psychiatric problem that is present on admission or develops during hospitalization and that is not specifically within the scope of practice, as defined by the medical staff and permitted by State law and as limited by paragraphs (c)(1) (iv) and (v) of this section, of any of the practitioners specified in paragraphs (c)(1) (ii) through (v) of this section.

(5)(i) To identify potential organ donors as defined in § 485.302 of this chapter, the hospital has written protocols that—

(A) Assure that the family of each potential organ donor knows of its option either to donate organs or tissues or to decline to donate;

(B) Encourage discretion and sensitivity with respect to the circumstances, views and beliefs of the families of potential donors; and

(C) Require that an organ procurement organization designated by the Secretary under § 485.308 of this chapter be notified of potential organ donors.

(ii) In the case of a hospital in which organ transplants are performed, the hospital must be a member of the Organ Procurement and Transplantation Network established under section 372 of the Public Health Service Act and abide by its rules and requirements.

(iii) For purposes of this subparagraph, the term "organ" means a human kidney, liver, heart, lung, or pancreas.

(d) *Standard: Institutional plan and budget.* The institution must have an overall institutional plan that meets the following conditions:

(1) The plan must include an annual operating budget that is prepared according to generally accepted accounting principles.

(2) The budget must include all anticipated income and expenses. This provision does not require that the budget identify item by item the components of each anticipated income or expense.

(3) The plan must provide for capital expenditures for at least a 3-year period, including the year in which the operating budget specified in paragraph (d)(2) of this section is applicable.

(4) The plan must include and identify in detail the objective of, and the anticipated sources of financing for, each anticipated capital expenditure in excess of $600,000 (or a lesser amount that is established, in accordance with section 1122(g)(1) of the Act, by the State in which the hospital is located) that relates to any of the following:

(i) Acquisition of land;

(ii) Improvement of land, buildings, and equipment; or

(iii) The replacement, modernization, and expansion of buildings and equipment.

(5) The plan must be submitted for review to the planning agency designated in accordance with section 1122(b) of the Act, or if an agency is not designated, to the appropriate health planning agency in the State. (See Part 100 of this title.) A capital expenditure is not subject to section 1122 review if 75 percent of the health care facility's patients who are expected to use the service for which the capital expenditure is made are individuals enrolled in a health maintenance organization (HMO) or competitive medical plan (CMP) that meets the requirements of section 1876(b) of the Act, and if the Department determines that the capital expenditure is for services and facilities that are needed by the HMO or CMP in order to operate efficiently and economically and that are not otherwise readily accessible to the HMO or CMP because—

(i) The facilities do not provide common services at the same site;

(ii) The facilities are not available under a contract of reasonable duration;

(iii) Full and equal medical staff privileges in the facilities are not available;

(iv) Arrangements with these facilities are not administratively feasible; or

(v) The purchase of these services is more costly than if the HMO or CMP provided the services directly.

(6) The plan must be reviewed and updated annually.

(7) The plan must be prepared—

(i) Under the direction of the governing body; and

(ii) By a committee consisting of representatives of the governing body, the administrative staff, and the medical staff of the institution.

(e) *Standard: Contracted services.* The governing body must be responsible for services furnished in the hospital whether or not they are furnished under contracts. The governing body must ensure that a contractor of services (including one for shared services and joint ventures) furnishes services that permit the hospital to comply with all applicable conditions of participation and standards for the contracted services.

(1) The governing body must ensure that the services performed under a contract are provided in a safe and effective manner.

(2) The hospital must maintain a list of all contracted services, including the scope and nature of the services provided.

(f) *Standard: Emergency services.* (1) If emergency services are provided at the hospital, the hospital must comply with the requirements of § 482.55.

(2) If emergency services are not provided at the hospital, the governing body must assure that the medical staff has written policies and procedures for appraisal of emergencies, initial treatment, and referral when appropriate.

[51 FR 22042, June 17, 1986; 51 FR 27847, Aug. 4, 1986, as amended at 53 FR 6549, Mar. 1, 1988; 53 FR 18987, May 26, 1988]

Subpart C—Basic Hospital Functions

§ 482.21 Condition of participation: Quality assurance.

The governing body must ensure that there is an effective, hospital-wide quality assurance program to evaluate the provision of patient care.

(a) *Standard: Clinical plan.* The organized, hospital-wide quality assurance program must be ongoing and have a written plan of implementation.

(1) All organized services related to patient care, including services furnished by a contractor, must be evaluated.

(2) Nosocomial infections and medication therapy must be evaluated.

(3) All medical and surgical services performed in the hospital must be evaluated as they relate to appropriateness of diagnosis and treatment.

(b) *Standard: Medically-related patient care services.* The hospital must have an ongoing plan, consistent with available community and hospital resources, to provide or make available social work, psychological, and educational services to meet the medically-related needs of its patients. The hospital also must have an effective, ongoing discharge planning program that facilitates the provision of followup care.

(1) Discharge planning must be initiated in a timely manner.

(2) Patients, along with necessary medical information, must be transferred or referred to appropriate facilities, agencies, or outpatient services, as needed, for followup or ancillary care.

(c) *Standard: Implementation.* The hospital must take and document appropriate remedial action to address deficiencies found through the quality assurance program. The hospital must document the outcome of the remedial action.

§ 482.22 Condition of participation: Medical staff.

The hospital must have an organized medical staff that operates under bylaws approved by the governing body and is responsible for the quality of medical care provided to patients by the hospital.

(a) *Standard: Composition of the medical staff.* The medical staff must be composed of doctors of medicine or osteopathy and, in accordance with State law, may also be composed of other practitioners appointed by the governing body.

(1) The medical staff must periodically conduct appraisals of its members.

(2) The medical staff must examine credentials of candidates for medical staff membership and make recommendations to the governing body on the appointment of the candidates.

(b) *Standard: Medical staff organization and accountability.* The medical staff must be well organized and accountable to the governing body for the quality of the medical care provided to patients.

(1) The medical staff must be organized in a manner approved by the governing body.

(2) If the medical staff has an executive committee, a majority of the members of the committee must be doctors of medicine or osteopathy.

(3) The responsibility for organization and conduct of the medical staff must be assigned only to an individual doctor of medicine or osteopathy.

(c) *Standard: Medical staff bylaws.* The medical staff must adopt and enforce bylaws to carry out its responsibilities. The bylaws must:

(1) Be approved by the governing body.

(2) Include a statement of the duties and privileges of each category of medical staff (e.g., active, courtesy, etc.)

(3) Describe the organization of the medical staff.

(4) Describe the qualifications to be met by a candidate in order for the medical staff to recommend that the candidate be appointed by the governing body.

(5) Include a requirement that a physical examination and medical history be done no more than 7 days before or 48 hours after an admission for each patient by a doctor of medicine or osteopathy, or, for patients admitted only for oromaxillofacial surgery, by an oromaxillofacial surgeon who has been granted such privileges by the medical staff in accordance with State law.

(6) Include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges.

(d) *Standard: Autopsies.* The medical staff should attempt to secure autopsies in all cases of unusual deaths and of medical-legal and educational interest. The mechanism for documenting permission to perform an autopsy must be defined. There must be a system for notifying the medical staff, and specifically the attending practitioner, when an autopsy is being performed.

§ 482.23 Condition of participation: Nursing services.

The hospital must have an organized nursing service that provides 24-hour nursing services. The nursing services must be furnished or supervised by a registered nurse.

(a) *Standard: Organization.* The hospital must have a well-organized service with a plan of administrative authority and delineation of responsibilities for patient care. The director of the nursing service must be a licensed registered nurse. He or she is responsible for the operation of the service, including determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the hospital.

(b) *Standard: Staffing and delivery of care.* The nursing service must have adequate numbers of licensed registered nurses, licensed practical (vocational) nurses, and other personnel to provide nursing care to all patients as needed. There must be supervisory and staff personnel for each department or nursing unit to ensure, when needed, the immediate availability of a registered nurse for bedside care of any patient.

(1) The hospital must provide 24-hour nursing services furnished or supervised by a registered nurse, and have a licensed practical nurse or registered nurse on duty at all times, except for rural hospitals that have in effect a 24-hour nursing waiver granted under § 405.1910(c) of this chapter.

(2) The nursing service must have a procedure to ensure that hospital nursing personnel for whom licensure is required have valid and current licensure.

(3) A registered nurse must supervise and evaluate the nursing care for each patient.

(4) The hospital must ensure that the nursing staff develops, and keeps current, a nursing care plan for each patient.

(5) A registered nurse must assign the nursing care of each patient to other nursing personnel in accordance with the patient's needs and the specialized qualifications and competence of the nursing staff available.

(6) Non-employee licensed nurses who are working in the hospital must adhere to the policies and procedures of the hospital. The director of nursing service must provide for the adequate supervision and evaluation of the clinical activities of non-employee nursing personnel which occur within the responsibility of the nursing service.

(c) *Standard: Preparation and administration of drugs.* Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient's care as specified under § 482.12(c), and accepted standards of practice.

(1) All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.

(2) All orders for drugs and biologicals must be in writing and signed by the practitioner or practitioners responsible for the care of the patient as specified under § 482.12(c). When telephone or oral orders must be used, they must be—

(i) Accepted only by personnel that are authorized to do so by the medical staff policies and procedures, consistent with Federal and State law;

(ii) Signed or initialed by the prescribing practitioner as soon as possible; and

(iii) Used infrequently.

(3) Blood transfusions and intravenous medications must be administered in accordance with State law and approved medical staff policies and procedures. If blood transfusions and intravenous medications are administered by personnel other than doctors of medicine or osteopathy, the personnel must have special training for this duty.

(4) There must be a hospital procedure for reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs.

§ 482.24 Condition of participation: Medical record services.

The hospital must have a medical record service that has administrative responsibility for medical records. A medical record must be maintained for every individual evaluated or treated in the hospital.

(a) *Standard: Organization and staffing.* The organization of the medical record service must be appropriate to the scope and complexity of the services performed. The hospital must employ adequate personnel to ensure prompt completion, filing, and retrieval of records.

(b) *Standard: Form and retention of record.* The hospital must maintain a medical record for each inpatient and outpatient. Medical records must be accurately written, promptly completed, properly filed and retained, and accessible. The hospital must use a system of author identification and record maintenance that ensures the integrity of the authentification and protects the security of all record entries.

(1) Medical records must be retained in their original or legally reproduced form for a period of at least 5 years.

(2) The hospital must have a system of coding and indexing medical records. The system must allow for timely retrieval by diagnosis and procedure, in order to support medical care evaluation studies.

(3) The hospital must have a procedure for ensuring the confidentiality of patient records. In-formation from or copies of records may be released only to authorized individuals, and the hospital must ensure that unauthorized individuals cannot gain access to or alter patient records. Original medical records must be released by the hospital only in accordance with Federal or State laws, court orders, or subpoenas.

(c) *Standard: Content of record.* The medical record must contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient's progress and response to medications and services.

(1) All entries must be legible and complete, and must be authenticated and dated promptly by the person (identified by name and discipline) who is responsible for ordering, providing, or evaluating the service furnished.

(i) The author of each entry must be identifed and must authenticate his or her entry.

(ii) Authentication may include signatures, written initials or computer entry.

(2) All records must document the following, as appropriate:

(i) Evidence of a physical examination, including a health history, performed no more than 7 days prior to admission or within 48 hours after admission.

(ii) Admitting diagnosis.

(iii) Results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient.

(iv) Documentation of complications, hospital acquired infections, and unfavorable reactions to drugs and anesthesia.

(v) Properly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, to require written patient consent.

(vi) All practitioners' orders, nursing notes, reports of treatment, medication records, radiology, and laboratory reports, and vital signs and other information necessary to monitor the patient's condition.

(vii) Discharge summary with outcome of hospitalization, disposition of case, and provisions for follow-up care.

(viii) Final diagnosis with completion of medical records within 30 days following discharge.

§ 482.25 Condition of participation: Pharmaceutical services.

The hospital must have pharmaceutical services that meet the needs of the patients. The institution must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service.

(a) *Standard: Pharmacy management and administration.* The pharmacy or drug storage area must be administered in accordance with accepted professional principles.

(1) A full-time, part-time, or consulting pharmacist must be responsible for developing, supervising, and coordinating all the activities of the pharmacy services.

(2) The pharmaceutical service must have an adequate number of personnel

to ensure quality pharmaceutical services, including emergency services.

(3) Current and accurate records must be kept of the receipt and disposition of all scheduled drugs.

(b) *Standard: Delivery of services.* In order to provide patient safety, drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice, consistent with Federal and State law.

(1) All compounding, packaging, and dispensing of drugs and biologicals must be under the supervision of a pharmacist and performed consistent with State and Federal laws.

(2) Drugs and biologicals must be kept in a locked storage area.

(3) Outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use.

(4) When a pharmacist is not available, drugs and biologicals must be removed from the pharmacy or storage area only by personnel designated in the policies of the medical staff and pharmaceutical service, in accordance with Federal and State law.

(5) Drugs and biologicals not specifically prescribed as to time or number of doses must automatically be stopped after a reasonable time that is predetermined by the medical staff.

(6) Drug administration errors, adverse drug reactions, and incompatibilities must be immediately reported to the attending physician and, if appropriate, to the hospital-wide quality assurance program.

(7) Abuses and losses of controlled substances must be reported, in accordance with applicable Federal and State laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate.

(8) Information relating to drug interactions and information of drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration must be available to the professional staff.

(9) A formulary system must be established by the medical staff to assure quality pharmaceuticals at reasonable costs.

[51 FR 22042, June 17, 1986; 51 FR 27848, Aug. 4, 1986]

§ 482.26 Condition of participation: Radiologic services.

The hospital must maintain, or have available, diagnostic radiologic services. If therapeutic services are also provided, they, as well as the diagnostic services, must meet professionally approved standards for safety and personnel qualifications.

(a) *Standard: Radiologic services.* The hospital must maintain, or have available, radiologic services according to needs of the patients.

(b) *Standard: Safety for patients and personnel.* The radiologic services, particularly ionizing radiology procedures, must be free from hazards for patients and personnel.

(1) Proper safety precutions must be maintained against radiation hazards. This includes adequate shielding for patients, personnel, and facilities, as well as appropriate storage, use, and disposal of radioactive materials.

(2) Periodic inspection of equipment must be made and hazards identified must be promptly corrected.

(3) Radiation workers must be checked periodically, by the use of exposure meters or badge tests, for amount of radiation exposure.

(4) Radiologic services must be provided only on the order of practitioners with clinical privileges or, consistent with State law, of other practitioners authorized by the medical staff and the governing body to order the services.

(c) *Standard: Personnel.* (1) A qualified full-time, part-time, or consulting radiologist must supervise the ionizing radiology services and must interpret only those radiologic tests that are determined by the medical staff to require a radiologist's specialized knowledge. For purposes of this section, a radiologist is a doctor of medicine or osteopathy who is qualified by education and experience in radiology.

(2) Only personnel designated as qualified by the medical staff may use the radiologic equipment and administer procedures.

(d) *Standard: Records.* Records of radiologic services must be maintained.

(1) The radiologist or other practitioner who performs radiology services

must sign reports of his or her interpretations.

(2) The hospital must maintain the following for at least 5 years:

(i) Copies of reports and printouts.

(ii) Films, scans, and other image records, as appropriate.

[51 FR 22042, June 17, 1986; 51 FR 27848, Aug. 4, 1986]

§ 482.27 Condition of participation: Laboratory services.

The hospital must maintain, or have available, adequate clinical laboratory services to meet the needs of its patients. The hospital must ensure that all laboratory services provided to its patients are performed in a Medicare approved facility.

(a) *Standard: Adequacy of laboratory services.* The hospital must have laboratory services available, either directly or through a contractual agreement with a Medicare approved hospital or independent laboratory, that meet the needs of the patients and the medical staff.

(1) Emergency laboratory services must be available 24 hours a day.

(2) A written description of services provided must be available to the medical staff.

(3) The laboratory must make provision for proper receipt and reporting of tissue specimens.

(i) The medical staff and a pathologist must determine which tissue specimens require a macroscopic (gross) examination and which require both macroscopic and microscopic examinations.

(ii) Except as specified in paragraphs (a)(3) (iii) and (iv) of this section, the tissue examination reports must be signed by a physician certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possessing qualifications that are equivalent to those required for certification (board eligible).

(iii) In the case of tests limited to skin pathology, the tissue examination reports may be signed by an individual—

(A) Certified in dermatopathology by the American Board of Dermatology, the American Osteopathic Board of Dermatology, the American Board of Pathology, or the American Osteopathic Board of Pathology; or

(B) Possessing qualifications that are equivalent to those required for certification (board eligible).

(iv) In the case of tests limited to oral pathology, the tissue examination reports may be signed by an individual—

(A) Certified in oral pathology by the American Board of Oral Pathology; or

(B) Possessing qualifications that are equivalent to those required for certification (board eligible).

(4) For emergency situations, the hospital must—

(i) Directly provide a minimum blood supply;

(ii) Have a list of donors and equipment to obtain blood quickly; or

(iii) Contract with blood banks or other institutions to obtain blood quickly.

(b) *Standard: Laboratory management.* The clinical laboratory must meet the management requirements specified in § 405.1316 of this chapter.

(c) *Standard: Personnel.* The facility must provide personnel to direct and conduct the laboratory services.

(1) The laboratory director must be technically qualified to supervise the laboratory personnel and test performance.

(i) The director must be a pathologist or other doctor of medicine or osteopathy with training and experience in clinical laboratory services, or a laboratory specialist with a doctoral degree in physical, chemical or biological sciences, and training and experience in clinical laboratory services.

(ii) If the laboratory performs anatomic pathology services, the tissue examination must be performed under the technical supervision of a pathologist or other individual who meets the requirements of paragraphs (a)(3) (iii) or (iv) of this section.

(iii) If the laboratory performs blood banking and transfusion services they must be performed under the technical supervision of a pathologist or other doctor of medicine or osteopathy with training and experience in transfusion therapy.

(2) The laboratory director must—

(i) Provide technical supervision of the laboratory services; and

(ii) Assure that tests, examinations, and procedures are properly performed, recorded, and reported.

(3) The laboratory director must ensure that the staff—

(i) Has appropriate education, experience, and training to perform and report laboratory tests promptly and proficiently;

(ii) Is sufficient in number for the scope and complexity of the services provided; and

(iii) Receives in-service training appropriate to the type and complexity of the laboratory services offered.

(4) The laboratory technologists must be technically competent to perform test procedures and report test results promptly and proficiently.

(d) *Standard: Blood and blood products.* The hospital must ensure that there are facilities for procurement, safe keeping, and transfusion of blood; and that blood products are provided or readily available.

(1) The hospital must maintain, as a minimum, proper blood storage facilities under adequate control and supervision of the pathologist or other authorized doctor of medicine or osteopathy.

(2) In the case of services provided by an outside blood bank, the hospital must have an agreement governing the procurement, transfer, and availability of blood that is reviewed and approved by the medical staff and administration.

(3) There must be provision for prompt blood grouping, antibody detection, and compatibility testing; and for laboratory investigation of transfusion reactions, either through the hospital or by arrangements with others on a continuous basis, under the supervision of a doctor of medicine or osteopathy.

(4) Blood storage facilities in the hospital must have an adequate temperature alarm system that is regularly inspected.

(5) According to the hospital's established procedures, samples of each unit of transfused blood must be retained for further testing in the event of reactions. The hospital must promptly dispose of blood not retained for further testing that has exceeded its expiration date.

(6) The hospital, according to its established procedures, must promptly investigate all transfusion reactions occurring in its own facility and make recommendations to the medical staff regarding improvements in transfusion procedures.

(e) *Standard: Proficiency testing.* The laboratory must meet the proficiency testing provisions specified in §§ 405.1310(c) and 405.1314(a) of this chapter.

(f) *Standard: Quality control.* The laboratory must meet the quality control requirements specified in § 405.1317 of this chapter.

[51 FR 22042, June 17, 1986; 51 FR 27848, Aug. 4, 1986]

§ 482.28 Condition of participation: Food and dietetic services.

The hospital must have organized dietary services that are directed and staffed by adequate qualified personnel. However, a hospital that has a contract with an outside food management company may be found to meet this Condition of participation if the company has a dietitian who serves the hospital on a full-time, part-time, or consultant basis, and if the company maintains at least the minimum standards specified in this section and provides for constant liaison with the hospital medical staff for recommendations on dietetic policies affecting patient treatment.

(a) *Standard: Organization.* (1) The hospital must have a full-time employee who—

(i) Serves as director of the food and dietetic service;

(ii) Is responsible for the daily management of the dietary services; and

(iii) Is qualified by experience or training.

(2) There must be a qualified dietitian, full-time, part-time, or on a consultant basis.

(3) There must be administrative and technical personnel competent in their respective duties.

(b) *Standard: Diets.* Menus must meet the needs of the patients.

(1) Therapeutic diets must be prescribed by the practitioner or practi-

tioners responsible for the care of the patients.

(2) Nutritional needs must be met in accordance with recognized dietary practices and in accordance with orders of the practitioner or practitioners responsible for the care of the patients.

(3) A current therapeutic diet manual approved by the dietitian and medical staff must be readily available to all medical, nursing, and food service personnel.

§ 482.30 Condition of participation: Utilization review.

The hospital must have in effect a utilization review (UR) plan that provides for review of services furnished by the institution and by members of the medical staff to patients entitled to benefits under the Medicare and Medicaid programs.

(a) *Applicability.* The provisions of this section apply except in either of the following circumstances:

(1) A Utilization and Quality Control Peer Review Organization (PRO) has assumed binding review for the hospital.

(2) HCFA has determined that the UR procedures established by the State under title XIX of the Act are superior to the procedures required in this section, and has required hospitals in that State to meet the UR plan requirements under §§ 456.50 through 456.245 of this chapter.

(b) *Standard: Composition of utilization review committee.* A UR committee consisting of two or more practitioners must carry out the UR function. At least two of the members of the committee must be doctors of medicine or osteopathy. The other members may be any of the other types of practitioners specified in § 482.12(c)(1).

(1) Except as specified in paragraphs (b) (2) and (3) of this section, the UR committee must be one of the following:

(i) A staff committee of the institution;

(ii) A group outside the institution—

(A) Established by the local medical society and some or all of the hospitals in the locality; or

(B) Established in a manner approved by HCFA.

(2) If, because of the small size of the institution, it is impracticable to have a properly functioning staff committee, the UR committee must be established as specified in paragraph (b)(1)(ii) of this section.

(3) The committee's or group's reviews may not be conducted by any individual who—

(i) Has a direct financial interest (for example, an ownership interest) in that hospital; or

(ii) Was professionally involved in the care of the patient whose case is being reviewed.

(c) *Standard: Scope and frequency of review.* (1) The UR plan must provide for review for Medicare and Medicaid patients with respect to the medical necessity of—

(i) Admissions to the institution;

(ii) The duration of stays; and

(iii) Professional services furnished, including drugs and biologicals.

(2) Review of admissions may be performed before, at, or after hospital admission.

(3) Except as specified in paragraph (e) of this section, reviews may be conducted on a sample basis.

(4) Hospitals that are paid for inpatient hospital services under the prospective payment system set forth in Part 412 of this chapter must conduct review of duration of stays and review of professional services as follows:

(i) For duration of stays, these hospitals need review only cases that they reasonably assume to be outlier cases based on extended length of stay, as described in § 412.80(a)(1)(i) of this chapter; and

(ii) For professional services, these hospitals need review only cases that they reasonably assume to be outlier cases based on extraordinarily high costs, as described in § 412.80(a)(1)(ii) of this chapter.

(d) *Standard: Determination regarding admissions or continued stays.* (1) The determination that an admission or continued stay is not medically necessary--

(i) May be made by one member of the UR committee if the practitioner or practitioners responsible for the care of the patient, as specified of

§ 482.12(c), concur with the determination or fail to present their views when afforded the opportunity; and

(ii) Must be made by at least two members of the UR committee in all other cases.

(2) Before making a determination that an admission or continued stay is not medically necessary, the UR committee must consult the practitioner or practitioners responsible for the care of the patient, as specified in § 482.12(c), and afford the practitioner or practitioners the opportunity to present their views.

(3) If the committee decides that admission to or continued stay in the hospital is not medically necessary, written notification must be given, no later than 2 days after the determination, to the hospital, the patient, and the practitioner or practitioners responsible for the care of the patient, as specified in § 482.12(c);

(e) *Standard: Extended stay review.* (1) In hospitals that are not paid under the prospective payment system, the UR committee must make a periodic review, as specified in the UR plan, of each current inpatient receiving hospital services during a continuous period of extended duration. The scheduling of the periodic reviews may—

(i) Be the same for all cases; or

(ii) Differ for different classes of cases.

(2) In hospitals paid under the prospective payment system, the UR committee must review all cases reasonably assumed by the hospital to be outlier cases because the extended length of stay exceeds the threshold criteria for the diagnosis, as described in § 412.80(a)(1)(i). The hospital is not required to review an extended stay that does not exceed the outlier threshold for the diagnosis.

(3) The UR committee must make the periodic review no later than 7 days after the day required in the UR plan.

(f) *Standard: Review of professional services.* The committee must review professional services provided, to determine medical necessity and to promote the most efficient use of available health facilities and services.

§ 482.41 Condition of participation: Physical environment.

The hospital must be constructed, arranged, and maintained to ensure the safety of the patient, and to provide facilities for diagnosis and treatment and for special hospital services appropriate to the needs of the community.

(a) *Standard: Buildings.* The condition of the physical plant and the overall hospital environment must be developed and maintained in such a manner that the safety and well-being of patients are assured.

(1) There must be emergency power and lighting in at least the operating, recovery, intensive care, and emergency rooms, and stairwells. In all other areas not serviced by the emergency supply source, battery lamps and flashlights must be available.

(2) There must be facilities for emergency gas and water supply.

(b) *Standard: Life safety from fire.* (1) Except as provided in paragraphs (b)(1)(i) through (b)(1)(iii) of this section, the hospital must meet the applicable provisions of the 1985 edition of the Life Safety Code of the National Fire Protection Association (which is incorporated by reference).[1]

(i) Any hospital that on November 26, 1982, complied, with or without waivers, with the requirements of the 1967 edition of the Life Safety Code, or on May 9, 1988, complied with the 1981 edition of the Life Safety Code, is considered to be in compliance with this standard as long as the facility continues to remain in compliance with that edition of the Code.

(ii) After consideration of State survey agency findings, HCFA may waive specific provisions of the Life Safety Code which, if rigidly applied, would result in unreasonable hardship upon the facility, but only if the waiver does not adversely affect the health and safety of patients.

(iii) The provisions of the Life Safety Code do not apply in a State where HCFA finds that a fire and safety code imposed by State law adequately protects patients in hospitals.

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[1] See footnote to § 405.1134(a) of this chapter.

(2) The hospital must have procedures for the proper routine storage and prompt disposal of trash.

(3) The hospital must have written fire control plans that contain provisions for prompt reporting of fires; extinguishing fires; protection of patients, personnel and guests; evacuation; and cooperation with fire fighting authorities.

(4) The hospital must maintain written evidence of regular inspection and approval by State or local fire control agencies.

(c) *Standard: Facilities.* The hospital must maintain adequate facilities for its services.

(1) Diagnostic and therapeutic facilities must be located for the safety of patients.

(2) Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.

(3) The extent and complexity of facilities must be determined by the services offered.

(4) There must be proper ventilation, light, and temperature controls in pharmaceutical, food preparation, and other appropriate areas.

[51 FR 22042, June 17, 1986, as amended at 53 FR 11509, Apr. 7, 1988]

§ 482.42 Condition of participation: Infection control.

The hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases.

(a) *Standard: Organization and policies.* A person or persons must be designated as infection control officer or officers to develop and implement policies governing control of infections and communicable diseases.

(1) The infection control officer or officers must develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel.

(2) The infection control officer or officers must maintain a log of incidents related to infections and communicable diseases.

(b) *Standard: Responsibilities of chief executive officer, medical staff, and director of nursing services.* The chief executive officer, the medical staff, and the director of nursing services must—

(1) Ensure that the hospital-wide quality assurance program and training programs address problems identified by the infection control officer or officers; and

(2) Be responsible for the implementation of successful corrective action plans in affected problem areas.

Subpart D—Optional Hospital Services

§ 482.51 Condition of participation: Surgical services.

If the hospital provides surgical services, the services must be well organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.

(a) *Standard: Organization and staffing.* The organization of the surgical services must be appropriate to the scope of the services offered.

(1) The operating rooms must be supervised by an experienced registered nurse or a doctor of medicine or osteopathy.

(2) Licensed practical nurses (LPNs) and surgical technologists (operating room technicians) may serve as "scrub nurses" under the supervision of a registered nurse.

(3) Qualified registered nurses may perform circulating duties in the operating room. In accordance with applicable State laws and approved medical staff policies and procedures, LPNs and surgical technologists may assist in circulatory duties under the supervision of a qualified registered nurse who is immediately available to respond to emergencies.

(4) Surgical privileges must be delineated for all practitioners performing surgery in accordance with the competencies of each practitioner. The surgical service must maintain a roster of

practitioners specifying the surgical privileges of each practitioner.

(b) *Standard: Delivery of service.* Surgical services must be consistent with needs and resources. Policies governing surgical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care.

(1) There must be a complete history and physical work-up in the chart of every patient prior to surgery, except in emergencies. If this has been dictated, but not yet recorded in the patient's chart, there must be a statement to that effect and an admission note in the chart by the practitioner who admitted the patient.

(2) A properly executed informed consent form for the operation must be in the patient's chart before surgery, except in emergencies.

(3) The following equipment must be available to the operating room suites: call-in-system, cardiac monitor, resuscitator, defibrillator, aspirator, and tracheotomy set.

(4) There must be adequate provisions for immediate post-operative care.

(5) The operating room register must be complete and up-to-date.

(6) An operative report describing techniques, findings, and tissues removed or altered must be written or dictated immediately following surgery and signed by the surgeon.

§ 482.52 Condition of participation: Anesthesia services.

If the hospital furnishes anesthesia services, they must be provided in a well-organized manner under the direction of a qualified doctor of medicine or osteopathy. The service is responsible for all anesthesia administered in the hospital.

(a) *Standard: Organization and staffing.* The organization of anesthesia services must be appropriate to the scope of the services offered. Anesthesia must be administered by only—

(1) A qualified anesthesiologist:

(2) A doctor of medicine or osteopathy (other than an anesthesiologist);

(3) A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law;

(4) A certified registered nurse anesthetist (CRNA) who is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed; or

(5) An anesthesiology assistant who is permitted by State law to administer anesthesia, who has successfully completed a 6-year program for anesthesiology assistants, 2 years of which consist of specialized academic and clinical training in anesthesia, and who is under the direct supervision of an anesthesiologist who is physically present.

(b) *Standard: Delivery of services.* Anesthesia services must be consistent with needs and resources. Policies on anesthesia procedures must include the delineation of preanesthesia and post anesthesia responsibilities. The policies must ensure that the following are provided for each patient:

(1) A preanesthesia evaluation by an individual qualified to administer anesthesia under paragraph (a) of this section performed within 48 hours prior to surgery.

(2) An intraoperative anesthesia record.

(3) With respect to inpatients, a postanesthesia followup report by the individual who administers the anesthesia that is written within 48 hours after surgery.

(4) With respect to outpatients, a postanesthesia evaluation for proper anesthesia recovery performed in accordance with policies and procedures approved by the medical staff.

§ 482.53 Condition of participation: Nuclear medicine services.

If the hospital provides nuclear medicine services, those services must meet the needs of the patients in accordance with acceptable standards of practice.

(a) *Standard: Organization and staffing.* The organization of the nuclear medicine service must be appropriate to the scope and complexity of the services offered.

(1) There must be a director who is a doctor of medicine or osteopathy qualified in nuclear medicine.

(2) The qualifications, training, functions, and responsibilities of nu-

clear medicine personnel must be specified by the service director and approved by the medical staff.

(b) *Standard: Delivery of service.* Radioactive materials must be prepared, labeled, used, transported, stored, and disposed of in accordance with acceptable standards of practice.

(1) In-house preparation of radiopharmaceuticals is by, or under, the direct supervision of an appropriately trained registered pharmacist or a doctor of medicine or osteopathy.

(2) There is proper storage and disposal of radioactive material.

(3) If clinical laboratory tests are performed in the nuclear medicine service, the service must meet the requirement for clinical laboratories with respect to management, adequacy of facilities, proficiency testing and quality control (see § 482.27 (a), (b), (e), and (f)).

(c) *Standard: Facilities.* Equipment and supplies must be appropriate for the types of nuclear medicine services offered and must be maintained for safe and efficient performance. The equipment must be—

(1) Maintained in safe operating condition; and

(2) Inspected, tested, and calibrated at least annually by qualified personnel.

(d) *Standard: Records.* The hospital must maintain signed and dated reports of nuclear medicine interpretations, consultations, and procedures.

(1) The hospital must maintain copies of nuclear medicine reports for at least 5 years.

(2) The practitioner approved by the medical staff to interpret diagnostic procedures must sign and date the interpretation of these tests.

(3) The hospital must maintain records of the receipt and disposition of radiopharmaceuticals.

(4) Nuclear medicine services must be ordered only by practitioner whose scope of Federal or State licensure and whose defined staff privileges allow such referrals.

§ 482.54 Condition of participation: Outpatient services.

If the hospital provides outpatient services, the services must meet the needs of the patients in accordance with acceptable standards of practice.

(a) *Standard: Organization.* Outpatient services must be appropriately organized and integrated with inpatient services.

(b) *Standard: Personnel.* The hospitals must—

(1) Assign an individual to be responsible for outpatient services; and

(2) Have appropriate professional and nonprofessional personnel available.

§ 482.55 Condition of participation: Emergency services.

The hospital must meet the emergency needs of patients in accordance with acceptable standards of practice.

(a) *Standard: Organization and direction.* If emergency services are provided at the hospital—

(1) The services must be organized under the direction of a qualified member of the medical staff;

(2) The services must be integrated with other departments of the hospital;

(3) The policies and procedures governing medical care provided in the emergency service or department are established by and are a continuing responsibility of the medical staff.

(b) *Standard: Personnel.* (1) The emergency services must be supervised by a qualified member of the medical staff.

(2) There must be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the facility.

§ 482.56 Condition of participation: Rehabilitation services.

If the hospital provides rehabilitation, physical therapy, occupational therapy, audiology, or speech pathology services, the services must be organized and staffed to ensure the health and safety of patients.

(a) *Standard: Organization and staffing.* The organization of the service must be appropriate to the scope of the services offered.

(1) The director of the services must have the necessary knowledge, experi-

ence, and capabilities to properly supervise and administer the services.

(2) Physical therapy, occupational therapy, or speech therapy, or audiology services, if provided, must be provided by staff who meet the qualifications specified by the medical staff, consistent with State law.

(b) *Standard: Delivery of services.* Services must be furnished in accordance with a written plan of treatment. Services must be given in accordance with orders of practitioners who are authorized by the medical staff to order the services, and the orders must be incorporated in the patient's record.

§ 482.57 Condition of participation: Respiratory care services.

The hospital must meet the needs of the patients in accordance with acceptable standards of practice. The following requirements apply if the hospital provides respiratory care service.

(a) *Standard: Organization and Staffing.* The organization of the respiratory care services must be appropriate to the scope and complexity of the services offered.

(1) There must be a director of respiratory care services who is a doctor of medicine or osteopathy with the knowledge experience, and capabilities to supervise and administer the service properly. The director may serve on either a full-time or part-time basis.

(2) There must be adequate numbers of respiratory therapists, respiratory therapy technicians, and other personnel who meet the qualifications specified by the medical staff, consistent with State law.

(b) *Standard: Delivery of Services.* Services must be delivered in accordance with medical staff directives.

(1) Personnel qualified to perform specific procedures and the amount of supervision required for personnel to carry out specific procedures must be designated in writing.

(2) If blood gases or other clinical laboratory tests are performed in the respiratory care unit, the unit must meet the requirements for clinical laboratories with respect to management, adequacy of facilities, proficiency testing, and quality control. (See § 482.27 (a), (b), (e) and (f) for requirements applicable to laboratories).

(3) Services must be provided only on, and in accordance with, the orders of a doctor of medicine or osteopathy.

[51 FR 22042, June 17, 1986; 51 FR 27848, Aug. 4, 1986]

Subpart E—Requirements for Specialty Hospitals

§ 482.60 Special provisions applying to psychiatric hospitals.

Psychiatric hospital must—

(a) Be primarily engaged in providing, by or under the supervision of a doctor of medicine or osteopathy, psychiatric services for the diagnosis and treatment of mentally ill persons;

(b) Meet the conditions of participation specified in §§ 482.1 through 482.23 and §§ 482.25 through 482.57;

(c) Maintain clinical records on all patients, including records sufficient to permit HCFA to determine the degree and intensity of treatment furnished to Medicare beneficiaries, as specified in § 482.61; and

(d) Meet the staffing requirements specified in § 482.62.

[51 FR 22042, June 17, 1986; 51 FR 27848, Aug. 4, 1986]

§ 482.61 Condition of participation: Special medical record requirements for psychiatric hospitals.

The medical records maintained by a psychiatric hospital must permit determination of the degree and intensity of the treatment provided to individuals who are furnished services in the institution.

(a) *Standard: Development of assessment/diagnostic data.* Medical records must stress the psychiatric components of the record, including history of findings and treatment provided for the psychiatric condition for which the patient is hospitalized.

(1) The identification data must include the patient's legal status.

(2) A provisional or admitting diagnosis must be made on every patient at the time of admission, and must include the diagnoses of intercurrent diseases as well as the psychiatric diagnoses.

(3) The reasons for admission must be clearly documented as stated by the patient and/or others significantly involved.

(4) The social service records, including reports of interviews with patients, family members, and others, must provide an assessment of home plans and family attitudes, and community resource contacts as well as a social history.

(5) When indicated, a complete neurological examination must be recorded at the time of the admission physical examination.

(b) *Standard: Psychiatric evaluation.* Each patient must receive a psychiatric evaluation that must—

(1) Be completed within 60 hours of admission;

(2) Include a medical history;

(3) Contain a record of mental status;

(4) Note the onset of illness and the circumstances leading to admission;

(5) Describe attitudes and behavior;

(6) Estimate intellectual functioning, memory functioning, and orientation; and

(7) Include an inventory of the patient's assets in descriptive, not interpretative, fashion.

(c) *Standard: Treatment plan.* (1) Each patient must have an individual comprehensive treatment plan that must be based on an inventory of the patient's strengths and disabilities. The written plan must include—

(i) A substantiated diagnosis;

(ii) Short-term and long-range goals;

(iii) The specific treatment modalities utilized;

(iv) The responsibilities of each member of the treatment team; and

(v) Adequate documentation to justify the diagnosis and the treatment and rehabilitation activities carried out.

(2) The treatment received by the patient must be documented in such a way to assure that all active therapeutic efforts are included.

(d) *Standard: Recording progress.* Progress notes must be recorded by the doctor of medicine or osteopathy responsible for the care of the patient as specified in § 482.12(c), nurse, social worker and, when appropriate, others significantly involved in active treatment modalities. The frequency of progress notes is determined by the condition of the patient but must be recorded at least weekly for the first 2 months and at least once a month thereafter and must contain recommendations for revisions in the treatment plan as indicated as well as precise assessment of the patient's progress in accordance with the original or revised treatment plan.

(e) *Standard: Discharge planning and discharge summary.* The record of each patient who has been discharged must have a discharge summary that includes a recapitulation of the patient's hospitalization and recommendations from appropriate services concerning follow-up or aftercare as well as a brief summary of the patient's condition on discharge.

[51 FR 22042, June 17, 1986; 51 FR 27848, Aug. 4, 1986]

§ 482.62 Condition of participation: Special staff requirements for psychiatric hospitals.

The hospital must have adequate numbers of qualified professional and supportive staff to evaluate patients, formulate written, individualized comprehensive treatment plans, provide active treatment measures, and engage in discharge planning.

(a) *Standard: Personnel.* The hospital must employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to:

(1) Evaluate patients;

(2) Formulate written individualized, comprehensive treatment plans;

(3) Provide active treatment measures; and

(4) Engage in discharge planning.

(b) *Standard: Director of inpatient psychiatric services; medical staff.* Inpatient psychiatric services must be under the supervision of a clinical director, service chief, or equivalent who is qualified to provide the leadership required for an intensive treatment program. The number and qualifications of doctors of medicine and osteopathy must be adequate to provide essential psychiatric services.

(1) The clinical director, service chief, or equivalent must meet the

training and experience requirements for examination by the American Board of Psychiatry and Neurology or the American Osteopathic Board of Neurology and Psychiatry.

(2) The director must monitor and evaluate the quality and appropriateness of services and treatment provided by the medical staff.

(c) *Standard: Availability of medical personnel.* Doctors of medicine or osteopathy and other appropriate professional personnel must be available to provide necessary medical and surgical diagnostic and treatment services. If medical and surgical diagnostic and treatment services are not available within the institution, the institution must have an agreement with an outside source of these services to ensure that they are immediately available or a satisfactory agreement must be established for transferring patients to a general hospital that participates in the Medicare program.

(d) *Standard: Nursing services.* The hospital must have a qualified director of psychiatric nursing services. In addition to the director of nursing, there must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide nursing care necessary under each patient's active treatment program and to maintain progress notes on each patient.

(1) The director of psychiatric nursing services must be a registered nurse who has a master's degree in psychiatric or mental health nursing, or its equivalent from a school of nursing accredited by the National League for Nursing, or be qualified by education and experience in the care of the mentally ill. The director must demonstrate competence to participate in interdisciplinary formulation of individual treatment plans; to give skilled nursing care and therapy; and to direct, monitor, and evaluate the nursing care furnished.

(2) The staffing pattern must insure the availability of a registered professional nurse 24 hours each day. There must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide the nursing care necessary under each patient's active treatment program.

(e) *Standard: Psychological services.* The hospital must provide or have available psychological services to meet the needs of the patients.

(f) *Standard: Social services.* There must be a director of social services who monitors and evaluates the quality and appropriateness of social services furnished. The services must be furnished in accordance with accepted standards of practice and established policies and procedures.

(1) The director of the social work department or service must have a master's degree from an accredited school of social work or must be qualified by education and experience in the social services needs of the mentally ill. If the director does not hold a masters degree in social work, at least one staff member must have this qualification.

(2) Social service staff responsibilities must include, but are not limited to, participating in discharge planning, arranging for follow-up care, and developing mechanisms for exchange of appropriate, information with sources outside the hospital.

(g) *Standard: Therapeutic activities.* The hospital must provide a therapeutic activities program.

(1) The program must be appropriate to the needs and interests of patients and be directed toward restoring and maintaining optimal levels of physical and psychosocial functioning.

(2) The number of qualified therapists, support personnel, and consultants must be adequate to provide comprehensive therapeutic activities consistent with each patient's active treatment program.

[51 FR 22042, June 17, 1986; 51 FR 27848, Aug. 4, 1986]

§ 482.66 Condition of participation—Special requirements for hospital providers of long-term care services ("swing-beds").

A hospital that has a Medicare provider agreement must meet the following requirements in order to be granted an approval from HCFA to provide post-hospital extended care services, as specified in § 409.30, and be reimbursed as a swing-bed hospital, as specified in § 413.114 of this chapter:

(a) *Standard: Eligibility.* A hospital must meet the following eligibility requirements:

(1) The facility has fewer than 50 hospital beds, excluding beds for newborns and beds in intensive care type inpatient units (for eligibility of hospitals with distinct parts electing the optional reimbursement method, see § 413.24(d)(5) of this chapter;

(2) The hospital is located in a rural area. This includes all areas not delineated as "urbanized" areas by the Census Bureau, based on the most recent census;

(3) When required by State in which it is located, the hospital has been granted a certificate of need for the provision of long-term care services from the State health planning and development agency (designated under section 1521 of the Public Health Service Act);

(4) The hospital does not have in effect a 24-hour nursing waiver granted under § 405.1910(c); and

(5) The hospital has not had a swing-bed approval terminated within the two years previous to application.

(b) *Standard: Skilled nursing facility services.* The facility is substantially in compliance with the following skilled nursing facility requirements contained in Subpart K of Part 405 of this chapter.

(1) Patients' rights (§ 405.1121(k) (2), (3), (4), (7), (8), (10), (11), (13), and (14));

(2) Specialized rehabilitative services (§ 405.1126 (a), (b), and (c));

(3) Dental services (§ 405.1129);

(4) Social services (§ 405.1130);

(5) Patient activities (§ 405.1131); and

(6) Discharge planning (§ 405.1137(h)).

[51 FR 22042, June 17, 1986; 51 FR 27848, Aug. 4, 1986, as amended at 51 FR 34833, Sept. 30, 1986]

PART 483—CONDITIONS OF PARTICIPATION FOR LONG TERM CARE FACILITIES

Subpart A-C—[Reserved]

Subpart D—Conditions of Participation for Intermediate Care Facilities for the Mentally Retarded

Sec.

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AUTHORITY: Secs. 1102, 1905(c) and (d) of the Social Security Act (42 U.S.C 1302, 1396d(c) and (d)).

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EFFECTIVE DATE NOTE: At 53 FR 20496, June 3, 1988, Part 483 was added, effective October 3, 1988.

Subpart A-C—[Reserved]

Subpart D—Conditions of Participation for Intermediate Care Facilities for the Mentally Retarded

§ 483.400 Basis and purpose.

This subpart implements section 1905 (c) and (d) of the Act which gives the Secretary authority to prescribe regulations for intermediate care facility services in facilities for the mentally retarded or persons with related conditions.

§ 483.405 Relationship to other HHS regulations.

In addition to compliance with the regulations set forth in this subpart, facilities are obliged to meet the applicable provisions of other HHS regulations, including but not limited to those pertaining to nondiscrimination on the basis of race, color, or national origin (45 CFR Part 80), nondiscrimination on the basis of handicap (45 CFR Part 84), nondiscrimination on the basis of age (45 CFR Part 91), protection of human subjects of research (45 CFR Part 46), and fraud and abuse (42 CFR Part 455). Although those regulations are not in themselves considered conditions of participation under this Part, their violation may result in the termination or suspension of, or the refusal to grant or continue, Federal financial assistance.

§ 483.410 Condition of participation: Governing body and management.

(a) *Standard: Governing body.* The facility must identify an individual or individuals to constitute the governing body of the facility. The governing body must—

(1) Exercise general policy, budget, and operating direction over the facility;

(2) Set the qualifications (in addition to those already set by State law, if any) for the administrator of the facility; and

(3) Appoint the administrator of the facility.

(b) *Standard: Compliance with Federal, State, and local laws.* The facility must be in compliance with all applicable provisions of Federal, State and local laws, regulations and codes pertaining to health, safety, and sanitation.

(c) *Standard: Client records.*

(1) The facility must develop and maintain a recordkeeping system that includes a separate record for each client and that documents the client's health care, active treatment, social information, and protection of the client's rights.

(2) The facility must keep confidential all information contained in the clients' records, regardless of the form or storage method of the records.

(3) The facility must develop and implement policies and procedures governing the release of any client information, including consents necessary from the client, or parents (if the client is a minor) or legal guardian.

(4) Any individual who makes an entry in a client's record must make it legibly, date it, and sign it.

(5) The facility must provide a legend to explain any symbol or abbreviation used in a client's record.

(6) The facility must provide each identified residential living unit with appropriate aspects of each client's record.

(d) *Standard: Services provided under agreements with outside sources.*

(1) If a service required under this subpart is not provided directly, the facility must have a written agreement with an outside program, resource, or service to furnish the necessary service, including emergency and other health care.

(2) The agreement must—

(i) Contain the responsibilities, functions, objectives, and other terms agreed to by both parties; and

(ii) Provide that the facility is responsible for assuring that the outside services meet the standards for quality of services contained in this subpart.

(3) The facility must assure that outside services meet the needs of each client.

(4) If living quarters are not provided in a facility owned by the ICF/MR, the ICF/MR remains directly responsible for the standards relating to physical environment that are specified in § 483.470 (a) through (g), (j) and (k).

§ 483.420 Condition of participation: Client protections.

(a) *Standard: Protection of clients' rights.* The facility must ensure the rights of all clients. Therefore, the facility must—

(1) Inform each client, parent (if the client is a minor), or legal guardian, of the client's rights and the rules of the facility;

(2) Inform each client, parent (if the client is a minor), or legal guardian, of the client's medical condition, developmental and behavioral status, attendant risks of treatment, and of the right to refuse treatment;

(3) Allow and encourage individual clients to exercise their rights as clients of the facility, and as citizens of

the United States, including the right to file complaints, and the right to due process;

(4) Allow individual clients to manage their financial affairs and teach them to do so to the extent of their capabilities;

(5) Ensure that clients are not subjected to physical, verbal, sexual or psychological abuse or punishment;

(6) Ensure that clients are free from unnecessary drugs and physical restraints and are provided active treatment to reduce dependency on drugs and physical restraints;

(7) Provide each client with the opportunity for personal privacy and ensure privacy during treatment and care of personal needs;

(8) Ensure that clients are not compelled to perform services for the facility and ensure that clients who do work for the facility are compensated for their efforts at prevailing wages and commensurate with their abilities;

(9) Ensure clients the opportunity to communicate, associate and meet privately with individuals of their choice, and to send and receive unopened mail;

(10) Ensure that clients have access to telephones with privacy for incoming and outgoing local and long distance calls except as contraindicated by factors identified within their individual program plans;

(11) Ensure clients the opportunity to participate in social, religious, and community group activities;

(12) Ensure that clients have the right to retain and use appropriate personal possessions and clothing, and ensure that each client is dressed in his or her own clothing each day; and

(13) Permit a husband and wife who both reside in the facility to share a room.

(b) *Standard: Client finances.* (1) The facility must establish and maintain a system that—

(i) Assures a full and complete accounting of clients' personal funds entrusted to the facility on behalf of clients; and

(ii) Precludes any commingling of client funds with facility funds or with the funds of any person other than another client.

(2) The client's financial record must be available on request to the client, parents (if the client is a minor) or legal guardian.

(c) *Standard: Communication with clients, parents, and guardians.* The facility must—

(1) Promote participation of parents (if the client is a minor) and legal guardians in the process of providing active treatment to a client unless their participation is unobtainable or inappropriate;

(2) Answer communications from clients' families and friends promptly and appropriately;

(3) Promote visits by individuals with a relationship to the client (such as family, close friends, legal guardians and advocates) at any reasonable hour, without prior notice, consistent with the right of that client's and other clients' privacy, unless the interdisciplinary team determines that the visit would not be appropriate;

(4) Promote visits by parents or guardians to any area of the facility that provides direct client care services to the client, consistent with the right of that client's and other clients' privacy;

(5) Promote frequent and informal leaves from the facility for visits, trips, or vacations; and

(6) Notify promptly the client's parents or guardian of any significant incidents, or changes in the client's condition including, but not limited to, serious illness, accident, death, abuse, or unauthorized absence.

(d) *Standard: Staff treatment of clients.* (1) The facility must develop and implement written policies and procedures that prohibit mistreatment, neglect or abuse of the client.

(i) Staff of the facility must not use physical, verbal, sexual or psychological abuse or punishment.

(ii) Staff must not punish a client by withholding food or hydration that contributes to a nutritionally adequate diet.

(iii) The facility must prohibit the employment of individuals with a conviction or prior employment history of child or client abuse, neglect or mistreatment.

(2) The facility must ensure that all allegations of mistreatment, neglect or

abuse, as well as injuries of unknown source, are reported immediately to the administrator or to other officials in accordance with State law through established procedures.

(3) The facility must have evidence that all alleged violations are thoroughly investigated and must prevent further potential abuse while the investigation is in progress.

(4) The results of all investigations must be reported to the administrator or designated representative or to other officials in accordance with State law within five working days of the incident and, if the alleged violation is verified, appropriate corrective action must be taken.

§ 483.430 Condition of participation: Facility staffing.

(a) *Standard: Qualified mental retardation professional.* Each client's active treatment program must be integrated, coordinated and monitored by a qualified mental retardation professional who—

(1) Has at least one year of experience working directly with persons with mental retardation or other developmental disabilities; and

(2) Is one of the following:

(i) A doctor of medicine or osteopathy.

(ii) A registered nurse.

(iii) An individual who holds at least a bachelor's degree in a professional category specified in paragraph (b)(5) of this section.

(b) *Standard: Professional program services.* (1) Each client must receive the professional program services needed to implement the active treatment program defined by each client's individual program plan. Professional program staff must work directly with clients and with paraprofessional, nonprofessional and other professional program staff who work with clients.

(2) The facility must have available enough qualified professional staff to carry out and monitor the various professional interventions in accordance with the stated goals and objectives of every individual program plan.

(3) Professional program staff must participate as members of the interdisciplinary team in relevant aspects of the active treatment process.

(4) Professional program staff must participate in on-going staff development and training in both formal and informal settings with other professional, paraprofessional, and nonprofessional staff members.

(5) Professional program staff must be licensed, certified, or registered, as applicable, to provide professional services by the State in which he or she practices. Those professional program staff who do not fall under the jurisdiction of State licensure, certification, or registration requirements, specified in § 483.410(b), must meet the following qualifications:

(i) To be designated as an occupational therapist, an individual must be eligible for certification as an occupational therapist by the American Occupational Therapy Association or another comparable body.

(ii) To be designated as an occupational therapy assistant, an individual must be eligible for certification as a certified occupational therapy assistant by the American Occupational Therapy Association or another comparable body.

(iii) To be designated as a physical therapist, an individual must be eligible for certification as a physical therapist by the American Physical Therapy Association or another comparable body.

(iv) To be designated as a physical therapy assistant, an individual must be eligible for registration by the American Physical Therapy Association or be a graduate of a two year college-level program approved by the American Physical Therapy Association or another comparable body.

(v) To be designated as a psychologist, an individual must have at least a master's degree in psychology from an accredited school.

(vi) To be designated as a social worker, an individual must—

(A) Hold a graduate degree from a school of social work accredited or approved by the Council on Social Work Education or another comparable body; or

(B) Hold a Bachelor of Social Work degree from a college or university accredited or approved by the Council on Social Work Education or another comparable body.

(vii) To be designated as a speech-language pathologist or audiologist, an individual must—

(A) Be eligible for a Certificate of Clinical Competence in Speech-Language Pathology or Audiology granted by the American Speech-Language-Hearing Association or another comparable body; or

(B) Meet the educational requirements for certification and be in the process of accumulating the supervised experience required for certification.

(viii) To be designated as a professional recreation staff member, an individual must have a bachelor's degree in recreation or in a specialty area such as art, dance, music or physical education.

(ix) To be designated as a professional dietitian, an individual must be eligible for registration by the American Dietetics Association.

(x) To be designated as a human services professional an individual must have at least a bachelor's degree in a human services field (including, but not limited to: sociology, special education, rehabilitation counseling, and psychology).

(xi) If the client's individual program plan is being successfully implemented by facility staff, professional program staff meeting the qualifications of paragraph (b)(5) (i) through (x) of this section are not required—

(A) Except for qualified mental retardation professionals;

(B) Except for the requirements of paragraph (b)(2) of this section concerning the facility's provision of enough qualified professional program staff; and

(C) Unless otherwise specified by State licensure and certification requirements.

(c) *Standard: Facility staffing.* (1) The facility must not depend upon clients or volunteers to perform direct care services for the facility.

(2) There must be responsible direct care staff on duty and awake on a 24-hour basis, when clients are present, to take prompt, appropriate action in case of injury, illness, fire or other emergency, in each defined residential living unit housing—

(i) Clients for whom a physician has ordered a medical care plan;

(ii) Clients who are aggressive, assaultive or security risks;

(iii) More than 16 clients; or

(iv) Fewer than 16 clients within a multi-unit building.

(3) There must be a responsible direct care staff person on duty on a 24 hour basis (when clients are present) to respond to injuries and symptoms of illness, and to handle emergencies, in each defined residential living unit housing—

(i) Clients for whom a physician has not ordered a medical care plan;

(ii) Clients who are not aggressive, assaultive or security risks; and

(iii) Sixteen or fewer clients,

(4) The facility must provide sufficient support staff so that direct care staff are not required to perform support services to the extent that these duties interfere with the exercise of their primary direct client care duties.

(d) *Standard: Direct care (residential living unit) staff.* (1) The facility must provide sufficient direct care staff to manage and supervise clients in accordance with their individual program plans.

(2) Direct care staff are defined as the present on-duty staff calculated over all shifts in a 24-hour period for each defined residential living unit.

(3) Direct care staff must be provided by the facility in the following minimum ratios of direct care staff to clients:

(i) For each defined residential living unit serving children under the age of 12, severely and profoundly retarded clients, clients with severe physical disabilities, or clients who are aggressive, assaultive, or security risks, or who manifest severely hyperactive or psychotic-like behavior, the staff to client ratio is 1 to 3.2.

(ii) For each defined residential living unit serving moderately retarded clients, the staff to client ratio is 1 to 4.

(iii) For each defined residential living unit serving clients who function within the range of mild retardation, the staff to client ratio is 1 to 6.4.

(4) When there are no clients present in the living unit, a responsi-

ble staff member must be available by telephone.

(e) *Standard: Staff training program.* (1) The facility must provide each employee with initial and continuing training that enables the employee to perform his or her duties effectively, efficiently, and competently.

(2) For employees who work with clients, training must focus on skills and competencies directed toward clients' developmental, behavioral, and health needs.

(3) Staff must be able to demonstrate the skills and techniques necessary to administer interventions to manage the inappropriate behavior of clients.

(4) Staff must be able to demonstrate the skills and techniques necessary to implement the individual program plans for each client for whom they are responsible.

§ 483.440 Condition of participation: Active treatment services.

(a) *Standard: Active treatment.* (1) Each client must receive a continuous active treatment program, which includes aggressive, consistent implementation of a program of specialized and generic training, treatment, health services and related services described in this subpart, that is directed toward—

(i) The acquisition of the behaviors necessary for the client to function with as much self determination and independence as possible; and

(ii) The prevention or deceleration of regression or loss of current optimal functional status.

(2) Active treatment does not include services to maintain generally independent clients who are able to function with little supervision or in the absence of a continuous active treatment program.

(b) *Standard: Admissions, transfers, and discharge.* (1) Clients who are admitted by the facility must be in need of and receiving active treatment services.

(2) Admission decisions must be based on a preliminary evaluation of the client that is conducted or updated by the facility or by outside sources.

(3) A preliminary evaluation must contain background information as well as currently valid assessments of functional developmental, behavioral, social, health and nutritional status to determine if the facility can provide for the client's needs and if the client is likely to benefit from placement in the facility.

(4) If a client is to be either transferred or discharged, the facility must—

(i) Have documentation in the client's record that the client was transferred or discharged for good cause; and

(ii) Provide a reasonable time to prepare the client and his or her parents or guardian for the transfer or discharge (except in emergencies).

(5) At the time of the discharge, the facility must—

(i) Develop a final summary of the client's developmental, behavioral, social, health and nutritional status and, with the consent of the client, parents (if the client is a minor) or legal guardian, provide a copy to authorized persons and agencies; and

(ii) Provide a post-discharge plan of care that will assist the client to adjust to the new living environment.

(c) *Standard: Individual program plan.* (1) Each client must have an individual program plan developed by an interdisciplinary team that represents the professions, disciplines or service areas that are relevant to—

(i) Identifying the client's needs, as described by the comprehensive functional assessments required in paragraph (c)(3) of this section; and

(ii) Designing programs that meet the client's needs.

(2) Appropriate facility staff must participate in interdisciplinary team meetings. Participation by other agencies serving the client is encouraged. Participation by the client, his or her parent (if the client is a minor), or the client's legal guardian is required unless that participation is unobtainable or inappropriate.

(3) Within 30 days after admission, the interdisciplinary team must perform accurate assessments or reassessments as needed to supplement the preliminary evaluation conducted prior to admission. The comprehensive functional assessment must take into consideration the client's age (for ex-

ample, child, young adult, elderly person) and the implications for active treatment at each stage, as applicable, and must—

(i) Identify the presenting problems and disabilities and where possible, their causes;

(ii) Identify the client's specific developmental strengths;

(iii) Identify the client's specific developmental and behavioral management needs;

(iv) Identify the client's need for services without regard to the actual availability of the services needed; and

(v) Include physical development and health, nutritional status, sensorimotor development, affective development, speech and language development and auditory functioning, cognitive development, social development, adaptive behaviors or independent living skills necessary for the client to be able to function in the community, and as applicable, vocational skills.

(4) Within 30 days after admission, the interdisciplinary team must prepare for each client an individual program plan that states the specific objectives necessary to meet the client's needs, as identified by the comprehensive assessment required by paragraph (c)(3) of this section, and the planned sequence for dealing with those objectives. These objectives must—

(i) Be stated separately, in terms of a single behavioral outcome;

(ii) Be assigned projected completion dates;

(iii) Be expressed in behavioral terms that provide measurable indices of performance;

(iv) Be organized to reflect a developmental progression appropriate to the individual; and

(v) Be assigned priorities.

(5) Each written training program designed to implement the objectives in the individual program plan must specify:

(i) The methods to be used;

(ii) The schedule for use of the method;

(iii) The person responsible for the program;

(iv) The type of data and frequency of data collection necessary to be able to assess progress toward the desired objectives;

(v) The inappropriate client behavior(s), if applicable; and

(vi) Provision for the appropriate expression of behavior and the replacement of inappropriate behavior, if applicable, with behavior that is adaptive or appropriate.

(6) The individual program plan must also:

(i) Describe relevant interventions to support the individual toward independence.

(ii) Identify the location where program strategy information (which must be accessible to any person responsible for implementation) can be found.

(iii) Include, for those clients who lack them, training in personal skills essential for privacy and independence (including, but not limited to, toilet training, personal hygiene, dental hygiene, self-feeding, bathing, dressing, grooming, and communication of basic needs), until it has been demonstrated that the client is developmentally incapable of acquiring them.

(iv) Identify mechanical supports, if needed, to achieve proper body position, balance, or alignment. The plan must specify the reason for each support, the situations in which each is to be applied, and a schedule for the use of each support.

(v) Provide that clients who have multiple disabling conditions spend a major portion of each waking day out of bed and outside the bedroom area, moving about by various methods and devices whenever possible.

(iv) Include opportunities for client choice and self-management.

(7) A copy of each client's individual program plan must be made available to all relevant staff, including staff of other agencies who work with the client, and to the client, parents (if the client is a minor) or legal guardian.

(d) *Standard: Program implementation.* (1) As soon as the interdisciplinary team has formulated a client's individual program plan, each client must receive a continuous active treatment program consisting of needed interventions and services in sufficient number and frequency to support the achievement of the objectives identified in the individual program plan.

(2) The facility must develop an active treatment schedule that outlines the current active treatment program and that is readily available for review by relevant staff.

(3) Except for those facets of the individual program plan that must be implemented only by licensed personnel, each client's individual program plan must be implemented by all staff who work with the client, including professional, paraprofessional and nonprofessional staff.

(e) *Standard: Program documentation.* (1) Data relative to accomplishment of the criteria specified in client individual program plan objectives must be documented in measureable terms.

(2) The facility must document significant events that are related to the client's individual program plan and assessments and that contribute to an overall understanding of the client's ongoing level and quality of functioning.

(f) *Standard: Program monitoring and change.* (1) The individual program plan must be reviewed at least by the qualified mental retardation professional and revised as necessary, including, but not limited to situations in which the client—

(i) Has successfully completed an objective or objectives identified in the individual program plan;

(ii) Is regressing or losing skills already gained;

(iii) Is failing to progress toward identified objectives after reasonable efforts have been made; or

(iv) Is being considered for training towards new objectives.

(2) At least annually, the comprehensive functional assessment of each client must be reviewed by the interdisciplinary team for relevancy and updated as needed, and the individual program plan must be revised, as appropriate, repeating the process set forth in paragraph (c) of this section.

(3) The facility must designate and use a specially constituted committee or committees consisting of members of facility staff, parents, legal guardians, clients (as appropriate), qualified persons who have either experience or training in contemporary practices to change inappropriate client behavior, and persons with no ownership or controlling interest in the facility to—

(i) Review, approve, and monitor individual programs designed to manage inappropriate behavior and other programs that, in the opinion of the committee, involve risks to client protection and rights;

(ii) Insure that these programs are conducted only with the written informed consent of the client, parent (if the client is a minor), or legal guardian; and

(iii) Review, monitor and make suggestions to the facility about its practices and programs as they relate to drug usage, physical restraints, time-out rooms, application of painful or noxious stimuli, control of inappropriate behavior, protection of client rights and funds, and any other area that the committee believes need to be addressed.

(4) The provisions of paragraph (f)(3) of this section may be modified only if, in the judgment of the State survey agency, Court decrees, State law or regulations provide for equivalent client protection and consultation.

§ 483.450 Condition of participation: Client behavior and facility practices.

(a) *Standard: Facility practices—Conduct toward clients.* (1) The facility must develop and implement written policies and procedures for the management of conduct between staff and clients. These policies and procedures must—

(i) Promote the growth, development and independence of the client;

(ii) Address the extent to which client choice will be accommodated in daily decision-making, emphasizing self-determination and self-management, to the extent possible;

(iii) Specify client conduct to be allowed or not allowed; and

(iv) Be available to all staff, clients, parents of minor children, and legal guardians.

(2) To the extent possible, clients must participate in the formulation of these policies and procedures.

(3) Clients must not discipline other clients, except as part of an organized

system of self-government, as set forth in facility policy.

(b) *Standard: Management of inappropriate client behavior.* (1) The facility must develop and implement written policies and procedures that govern the management of inappropriate client behavior. These policies and procedures must be consistent with the provisions of paragraph (a) of this section. These procedures must—

(i) Specify all facility approved interventions to manage inappropriate client behavior;

(ii) Designate these interventions on a hierarchy to be implemented, ranging from most positive or least intrusive, to least positive or most intrusive;

(iii) Insure, prior to the use of more restrictive techniques, that the client's record documents that programs incorporating the use of less intrusive or more positive techniques have been tried systematically and demonstrated to be ineffective; and

(iv) Address the following:

(A) The use of time-out rooms.

(B) The use of physical restraints.

(C) The use of drugs to manage inappropriate behavior.

(D) The application of painful or noxious stimuli.

(E) The staff members who may authorize the use of specified interventions.

(F) A mechanism for monitoring and controlling the use of such interventions.

(2) Interventions to manage inappropriate client behavior must be employed with sufficient safeguards and supervision to ensure that the safety, welfare and civil and human rights of clients are adequately protected.

(3) Techniques to manage inappropriate client behavior must never be used for disciplinary purposes, for the convenience of staff or as a substitute for an active treatment program.

(4) The use of systematic interventions to manage inappropriate client behavior must be incorporated into the client's individual program plan, in accordance with § 483.440(c) (4) and (5) of this subpart.

(5) Standing or as needed programs to control inappropriate behavior are not permitted.

(c) *Standard: Time-out rooms.* (1) A client may be placed in a room from which egress is prevented only if the following conditions are met:

(i) The placement is a part of an approved systematic time-out program as required by paragraph (b) of this section. (Thus, emergency placement of a client into a time-out room is not allowed.)

(ii) The client is under the direct constant visual supervision of designated staff.

(iii) The door to the room is held shut by staff or by a mechanism requiring constant physical pressure from a staff member to keep the mechanism engaged.

(2) Placement of a client in a time-out room must not exceed one hour.

(3) Clients placed in time-out rooms must be protected from hazardous conditions including, but not limited to, presence of sharp corners and objects, uncovered light fixtures, unprotected electrical outlets.

(4) A record of time-out activities must be kept.

(d) *Standard: Physical restraints.* (1) The facility may employ physical restraint only—

(i) As an integral part of an individual program plan that is intended to lead to less restrictive means of managing and eliminating the behavior for which the restraint is applied;

(ii) As an emergency measure, but only if absolutely necessary to protect the client or others from injury; or

(iii) As a health-related protection prescribed by a physician, but only if absolutely necessary during the conduct of a specific medical or surgical procedure, or only if absolutely necessary for client protection during the time that a medical condition exists.

(2) Authorizations to use or extend restraints as an emergency must be:

(i) In effect no longer than 12 consecutive hours; and

(ii) Obtained as soon as the client is restrained or stable.

(3) The facility must not issue orders for restraint on a standing or as needed basis.

(4) A client placed in restraint must be checked at least every 30 minutes by staff trained in the use of restraints, released from the restraint as

quickly as possible, and a record of these checks and usage must be kept.

(5) Restraints must be designed and used so as not to cause physical injury to the client and so as to cause the least possible discomfort.

(6) Opportunity for motion and exercise must be provided for a period of not less than 10 minutes during each two hour period in which restraint is employed, and a record of such activity must be kept.

(7) Barred enclosures must not be more than three feet in height and must not have tops.

(e) *Standard: Drug usage.* (1) The facility must not use drugs in doses that interfere with the individual client's daily living activities.

(2) Drugs used for control of inappropriate behavior must be approved by the interdisciplinary team and be used only as an integral part of the client's individual program plan that is directed specifically towards the reduction of and eventual elimination of the behaviors for which the drugs are employed.

(3) Drugs used for control of inappropriate behavior must not be used until it can be justified that the harmful effects of the behavior clearly outweigh the potentially harmful effects of the drugs.

(4) Drugs used for control of inappropriate behavior must be—

(i) Monitored closely, in conjunction with the physician and the drug regimen review requirement at § 483.460(j), for desired responses and adverse consequences by facility staff; and

(ii) Gradually withdrawn at least annually in a carefully monitored program conducted in conjunction with the interdisciplinary team, unless clinical evidence justifies that this is contraindicated.

§ 483.460 Condition of participation: Health care services.

(a) *Standard: Physician services.*

(1) The facility must ensure the availability of physician services 24 hours a day.

(2) The physician must develop, in coordination with licensed nursing personnel, a medical care plan of treatment for a client if the physician determines that an individual client requires 24-hour licensed nursing care. This plan must be integrated in the individual program plan.

(3) The facility must provide or obtain preventive and general medical care as well as annual physical examinations of each client that at a minimum include the following:

(i) Evaluation of vision and hearing.

(ii) Immunizations, using as a guide the recommendations of the Public Health Service Advisory Commitee on Immunization Practices or of the Committee on the Control of Infectious Diseases of the American Academy of Pediatrics.

(iii) Routine screening laboratory examinations as determined necessary by the physician, and special studies when needed.

(iv) Tuberculosis control, appropriate to the facility's population, and in accordance with the recommendations of the American College of Chest Physicians or the section of diseases of the chest of the American Academy of Pediatrics, or both.

(4) To the extent permitted by State law, the facility may utilize physician assistants and nurse practitioners to provide physician services as described in this section.

(b) *Standard: Physician participation in the individual program plan.* A physician must participate in—

(1) The establishment of each newly admitted client's initial individual program plan as required by § 456.380 of this chapter that specified plan of care requirements for ICFs; and

(2) If appropriate, physicians must participate in the review and update of an individual program plan as part of the interdisciplinary team process either in person or through written report to the interdisciplinary team.

(c) *Standard: Nursing services.* The facility must provide clients with nursing services in accordance with their needs. These services must include—

(1) Participation as appropriate in the development, review, and update of an individual program plan as part of the interdisciplinary team process;

(2) The development, with a physician, of a medical care plan of treatment for a client when the physician

has determined that an individual client requires such a plan;

(3) For those clients certified as not needing a medical care plan, a review of their health status which must—

(i) Be by a direct physical examination;

(ii) Be by a licensed nurse;

(iii) Be on a quarterly or more frequent basis depending on client need;

(iv) Be recorded in the client's record; and

(v) Result in any necessary action (including referral to a physician to address client health problems).

(4) Other nursing care as prescribed by the physician or as identified by client needs; and

(5) Implementing, with other members of the interdisciplinary team, appropriate protective and preventive health measures that include, but are not limited to—

(i) Training clients and staff as needed in appropriate health and hygiene methods;

(ii) Control of communicable diseases and infections, including the instruction of other personnel in methods of infection control; and

(iii) Training direct care staff in detecting signs and symptoms of illness or dysfunction, first aid for accidents or illness, and basic skills required to meet the health needs of the clients.

(d) *Standard: Nursing staff.* (1) Nurses providing services in the facility must have a current license to practice in the State.

(2) The facility must employ or arrange for licensed nursing services sufficient to care for clients health needs including those clients with medical care plans.

(3) The facility must utilize registered nurses as appropriate and required by State law to perform the health services specified in this section.

(4) If the facility utilizes only licensed practical or vocational nurses to provide health services, it must have a formal arrangement with a registered nurse to be available for verbal or onsite consultation to the licensed practical or vocational nurse.

(5) Non-licensed nursing personnel who work with clients under a medical care plan must do so under the supervision of licensed persons.

(e) *Standard: Dental services.* (1) The facility must provide or make arrangements for comprehensive diagnostic and treatment services for each client from qualified personnel, including licensed dentists and dental hygienists either through organized dental services in-house or through arrangement.

(2) If appropriate, dental professionals must participate, in the development, review and update of an individual program plan as part of the interdisciplinary process either in person or through written report to the interdisciplinary team.

(3) The facility must provide education and training in the maintenance of oral health.

(f) *Standard: Comprehensive dental diagnostic services.* Comprehensive dental diagnostic services include—

(1) A complete extraoral and intraoral examination, using all diagnostic aids necessary to properly evaluate the client's oral condition, not later than one month after admission to the facility (unless the examination was completed within twelve months before admission);

(2) Periodic examination and diagnosis performed at least annually, including radiographs when indicated and detection of manifestations of systemic disease; and

(3) A review of the results of examination and entry of the results in the client's dental record.

(g) *Standard: Comprehensive dental treatment.* The facility must ensure comprehensive dental treatment services that include—

(1) The availability for emergency dental treatment on a 24-hour-a-day basis by a licensed dentist; and

(2) Dental care needed for relief of pain and infections, restoration of teeth, and maintenance of dental health.

(h) *Standard: Documentation of dental services.* (1) If the facility maintains an in-house dental service, the facility must keep a permanent dental record for each client, with a dental summary maintained in the client's living unit.

(2) If the facility does not maintain an in-house dental service, the facility must obtain a dental summary of the results of dental visits and maintain the summary in the client's living unit.

(i) *Standard: Pharmacy services.* The facility must provide or make arrangements for the provision of routine and emergency drugs and biologicals to its clients. Drugs and biologicals may be obtained from community or contract pharmacists or the facility may maintain a licensed pharmacy.

(j) *Standard: Drug regimen review.* (1) A pharmacist with input from the interdisciplinary team must review the drug regimen of each client at least quarterly.

(2) The pharmacist must report any irregularities in clients' drug regimens to the prescribing physician and interdisciplinary team.

(3) The pharmacist must prepare a record of each client's drug regimen reviews and the facility must maintain that record.

(4) An individual medication administration record must be maintained for each client.

(5) As appropriate the pharmacist must participate in the development, implementation, and review of each client's individual program plan either in person or through written report to the interdisciplinary team.

(k) *Standard: Drug administration.* The facility must have an organized system for drug administration that identifies each drug up to the point of administration. The system must assure that—

(1) All drugs are administered in compliance with the physician's orders;

(2) All drugs, including those that are self-administered, are administered without error;

(3) Unlicensed personnel are allowed to administer drugs only if State law permits;

(4) Clients are taught how to administer their own medications if the interdisciplinary team determines that self administration of medications is an appropriate objective, and if the physician does not specify otherwise;

(5) The client's physician is informed of the interdisciplinary team's decision that self-administration of medications is an objective for the client;

(6) No client self-administers medications until he or she demonstrates the competency to do so;

(7) Drugs used by clients while not under the direct care of the facility are packaged and labeled in accordance with State law; and

(8) Drug administration errors and adverse drug reactions are recorded and reported immediately to a physician.

(l) *Standard: Drug storage and recordkeeping.* (1) The facility must store drugs under proper conditions of sanitation, temperature, light, humidity, and security.

(2) The facility must keep all drugs and biologicals locked except when being prepared for administration. Only authorized persons may have access to the keys to the drug storage area. Clients who have been trained to self administer drugs in accordance with § 483.460(k)(4) may have access to keys to their individual drug supply.

(3) The facility must maintain records of the receipt and disposition of all controlled drugs.

(4) The facility must, on a sample basis, periodically reconcile the receipt and disposition of all controlled drugs in schedules II through IV (drugs subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. 801 *et seq.*, as implemented by 21 CFR Part 308).

(5) If the facility maintains a licensed pharmacy, the facility must comply with the regulations for controlled drugs.

(m) *Standard: Drug labeling.* (1) Labeling of drugs and biologicals must—

(i) Be based on currently accepted professional principles and practices; and

(ii) Include the appropriate accessory and cautionary instructions, as well as the expiration date, if applicable.

(2) The facility must remove from use—

(i) Outdated drugs; and

(ii) Drug containers with worn, illegible, or missing labels.

(3) Drugs and biologicals packaged in containers designated for a particular client must be immediately re-

moved from the client's current medication supply if discontinued by the physician.

(n) *Standard: Laboratory services.* (1) For purposes of this section, "laboratory" means an entity for the microbiological, serological, chemical, hematological, radiobioassay, cytological, immunohematological, pathological or other examination of materials derived from the human body, for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or assessment of a medical condition.

(2) If a facility chooses to provide laboratory services, the laboratory must—

(i) Meet the management requirements specified in § 405.1316 of this chapter; and

(ii) Provide personnel to direct and conduct the laboratory services.

(A) The laboratory director must be technically qualified to supervise the laboratory personnel and test performance and must meet licensing or other qualification standards established by the State with respect to directors of clinical laboratories. For those States that do not have licensure or qualification requirements pertaining to directors of clinical laboratories, the director must be either—

(*1*) A pathologist or other doctor of medicine or osteopathy with training and experience in clinical laboratory services; or

(*2*) A laboratory specialist with a doctoral degree in physical, chemical or biological sciences, and training and experience in clinical laboratory services.

(B) The laboratory director must provide adequate technical supervision of the laboratory services and assure that tests, examinations and procedures are properly performed, recorded and reported.

(C) The laboratory director must ensure that the staff—

(*1*) Has appropriate education, experience, and training to perform and report laboratory tests promptly and proficiently;

(*2*) Is sufficient in number for the scope and complexity of the services provided; and

(*3*) Receives in-service training appropriate to the type and complexity of the laboratory services offered.

(D) The laboratory technologists must be technically competent to perform test procedures and report test results promptly and proficiently.

(3) The laboratory must meet the proficiency testing requirements specified in § 405.1314(a) of this chapter.

(4) The laboratory must meet the quality control requirements specified in § 405.1317 of this chapter.

(5) If the laboratory chooses to refer specimens for testing to another laboratory, the referral laboratory must be approved by the Medicare program either as a hospital or an independent laboratory.

§ 483.470 Condition of participation: Physical environment.

(a) *Standard: Client living environment.* (1) The facility must not house clients of grossly different ages, developmental levels, and social needs in close physical or social proximity unless the housing is planned to promote the growth and development of all those housed together.

(2) The facility must not segregate clients solely on the basis of their physical disabilities. It must integrate clients who have ambulation deficits or who are deaf, blind, or have seizure disorders, etc., with others of comparable social and intellectual development.

(b) *Standard: Client bedrooms.* (1) Bedrooms must—

(i) Be rooms that have at least one outside wall;

(ii) Be equipped with or located near toilet and bathing facilities;

(iii) Accommodate no more than four clients unless granted a variance under paragraph (b)(3) of this section;

(iv) Measure at least 60 square feet per client in multiple client bedrooms and at least 80 square feet in single client bedrooms; and

(v) In all facilities initially certified, or in buildings constructed or with major renovations or conversions on or after October 3, 1988, have walls that extend from floor to ceiling.

(2) If a bedroom is below grade level, it must have a window that—

(i) Is usable as a second means of escape by the client(s) occupying the room; and

(ii) Is no more than 44 inches (measured to the window sill) above the floor unless the facility is surveyed under the Health Care Occupancy Chapter of the Life Safety Code, in which case the window must be no more than 36 inches (measured to the window sill) above the floor.

(3) The survey agency may grant a variance from the limit of four clients per room only if a physician who is a member of the interdisciplinary team and who is a qualified mental retardation professional—

(i) Certifies that each client to be placed in a bedroom housing more than four persons is so severely medically impaired as to require direct and continuous monitoring during sleeping hours; and

(ii) Documents the reasons why housing in a room of only four or fewer persons would not be medically feasible.

(4) The facility must provide each client with—

(i) A separate bed of proper size and height for the convenience of the client;

(ii) A clean, comfortable, mattress;

(iii) Bedding appropriate to the weather and climate; and

(iv) Functional furniture appropriate to the client's needs, and individual closet space in the client's bedroom with clothes racks and shelves accessible to the client.

(c) *Standard: Storage space in bedroom.* The facility must provide—

(1) Space and equipment for daily out-of-bed activity for all clients who are not yet mobile, except those who have a short-term illness or those few clients for whom out-of-bed activity is a threat to health and safety; and

(2) Suitable storage space, accessible to clients, for personal possessions, such as TVs, radios, prosthetic equipment and clothing.

(d) *Standard: Client bathrooms.* The facility must—

(1) Provide toilet and bathing facilities appropriate in number, size, and design to meet the needs of the clients;

(2) Provide for individual privacy in toilets, bathtubs, and showers; and

(3) In areas of the facility where clients who have not been trained to regulate water temperature are exposed to hot water, ensure that the temperature of the water does not exceed 110° Fahrenheit.

(e) *Standard: Heating and ventilation.* (1) Each client bedroom in the facility must have—

(i) At least one window to the outside; and

(ii) Direct outside ventilation by means of windows, air conditioning, or mechanical ventilation.

(2) The facility must—

(i) Maintain the temperature and humidity within a normal comfort range by heating, air conditioning or other means; and

(ii) Ensure that the heating apparatus does not constitute a burn or smoke hazard to clients.

(f) *Standard: Floors.* The facility must have—

(1) Floors that have a resilient, nonabrasive, and slip-resistant surface;

(2) Nonabrasive carpeting, if the area used by clients is carpeted and serves clients who lie on the floor or ambulate with parts of their bodies, other than feet, touching the floor; and

(3) Exposed floor surfaces and floor coverings that promote mobility in areas used by clients, and promote maintenance of sanitary conditions

(g) *Standard: Space and equipment.* The facility must—

(1) Provide sufficient space and equipment in dining, living, health services, recreation, and program areas (including adequately equipped and sound treated areas for hearing and other evaluations if they are conducted in the facility) to enable staff to provide clients with needed services as required by this subpart and as identified in each client's individual program plan.

(2) Furnish, maintain in good repair, and teach clients to use and to make informed choices about the use of dentures, eyeglasses, hearing and other communications aids, braces, and other devices identified by the interdisciplinary team as needed by the client.

(3) Provide adequate clean linen and dirty linen storage areas.

(h) *Standard: Emergency plan and procedures.* (1) The facility must develop and implement detailed written plans and procedures to meet all potential emergencies and disasters such as fire, severe weather, and missing clients.

(2) The facility must communicate, periodically review, make the plan available, and provide training to the staff.

(i) *Standard: Evacuation drills.* (1) The facility must hold evacuation drills at least quarterly for each shift of personnel and under varied conditions to—

(i) Ensure that all personnel on all shifts are trained to perform assigned tasks;

(ii) Ensure that all personnel on all shifts are familiar with the use of the facility's fire protection features; and

(iii) Evaluate the effectiveness of emergency and disaster plans and procedures.

(2) The facility must—

(i) Actually evacuate clients during at least one drill each year on each shift;

(ii) Make special provisions for the evacuation of clients with physical disabilities;

(iii) File a report and evaluation on each evacuation drill;

(iv) Investigate all problems with evacuation drills, including accidents, and take corrective action; and

(v) During fire drills, clients may be evacuated to a safe area in facilities certified under the Health Care Occupancies Chapter of the Life Safety Code.

(3) Facilities must meet the requirements of paragraphs (i)(1) and (2) of this section for any live-in and relief staff they utilize.

(j) *Standard: Fire protection*—(1) *General.* (i) Except as specified in paragraph (j)(2) of this section, the facility must meet the applicable provisions of either the Health Care Occupancies Chapters or the Residential Board and Care Occupancies Chapter of the Life Safety Code (LSC) of the National Fire Protection Association, 1985 edition, which is incorporated by reference.[2]

(ii) The State survey agency may apply a single chapter of the LSC to the entire facility or may apply different chapters to different buildings or parts of buildings as permitted by the LSC.

(iii) A facility that meets the LSC definition of a residential board and care occupancy and that has 16 or fewer beds, must have its evacuation capability evaluated in accordance with the Evacuation Difficulty Index of the LSC (Appendix F).

(2) *Exceptions.* (i) For facilities that meet the LSC definition of a health care occupancy:

(A) The State survey agency may waive, for a period it considers appropriate, specific provisions of the LSC if—

(*1*) The waiver would not adversely affect the health and safety of the clients; and

(*2*) Rigid application of specific provisions would result in an unreasonable hardship for the facility.

(B) The State survey agency may apply the State's fire and safety code instead of the LSC if the Secretary finds that the State has a code imposed by State law that adequately protects a facility's clients.

(C) Compliance on November 26, 1982 with the 1967 edition of the LSC or compliance on April 18, 1986 with the 1981 edition of the LSC, with or without waivers, is considered to be compliance with this standard as long as the facility continues to remain in compliance with that edition of the Code.

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[2] Incorporation of the 1985 edition of the National Fire Protection Association's Life Safety Code (published February 7, 1985; ANSI/NFPA 101) was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51 that govern the use of incorporations by reference. The Code is available for inspection at the Office of the Federal Register Information Center, Room 8401, 1100 L Street NW., Washington, DC. Copies may be obtained from the National Fire Protection Association, Batterymarch Park, Quincy, Mass 02269.

If any changes in this Code are also to be incorporated by reference, a notice to that effect will be published in the Federal Register.

(ii) For facilities that meet the LSC definition of a residential board and care occupancy and that have more than 16 beds, the State survey agency may apply the State's fire and safety code as specified in paragraph (j)(2)(B) of this section.

(k) *Standard: Paint.* The facility must—

(1) Use lead-free paint inside the facility; and

(2) Remove or cover interior paint or plaster containing lead so that it is not accessible to clients.

(l) *Standard: Infection control.*

(1) The facility must provide a sanitary environment to avoid sources and transmission of infections. There must be an active program for the prevention, control, and investigation of infection and communicable diseases.

(2) The facility must implement successful corrective action in affected problem areas.

(3) The facility must maintain a record of incidents and corrective actions related to infections.

(4) The facility must prohibit employees with symptoms or signs of a communicable disease from direct contact with clients and their food.

§ 483.480 Condition of participation: Dietetic services.

(a) *Standard: Food and nutrition services.* (1) Each client must receive a nourishing, well-balanced diet including modified and specially-prescribed diets.

(2) A qualified dietitian must be employed either full-time, part-time, or on a consultant basis at the facility's discretion.

(3) If a qualified dietitian is not employed full-time, the facility must designate a person to serve as the director of food services.

(4) The client's interdisciplinary team, including a qualified dietitian and physician, must prescribe all modified and special diets including those used as a part of a program to manage inappropriate client behavior.

(5) Foods proposed for use as a primary reinforcement of adaptive behavior are evaluated in light of the client's nutritional status and needs.

(6) Unless otherwise specified by medical needs, the diet must be prepared at least in accordance with the latest edition of the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences, adjusted for age, sex, disability and activity.

(b) *Standard: Meal services.* (1) Each client must receive at least three meals daily, at regular times comparable to normal mealtimes in the community with—

(i) Not more than 14 hours between a substantial evening meal and breakfast of the following day, except on weekends and holidays when a nourishing snack is provided at bedtime, 16 hours may elapse between a substantial evening meal and breakfast; and

(ii) Not less than 10 hours between breakfast and the evening meal of the same day, except as provided under paragraph (b)(1)(i) of this section.

(2) Food must be served—

(i) In appropriate quantity;

(ii) At appropriate temperature;

(iii) In a form consistent with the developmental level of the client; and

(iv) With appropriate utensils.

(3) Food served to clients individually and uneaten must be discarded.

(c) *Standard: Menus.* (1) Menus must—

(i) Be prepared in advance;

(ii) Provide a variety of foods at each meal;

(iii) Be different for the same days of each week and adjusted for seasonal changes; and

(iv) Include the average portion sizes for menu items.

(2) Menus for food actually served must be kept on file for 30 days.

(d) *Standard: Dining areas and service.*

The facility must—

(1) Serve meals for all clients, including persons with ambulation deficits, in dining areas, unless otherwise specified by the interdisciplinary team or a physician;

(2) Provide table service for all clients who can and will eat at a table, including clients in wheelchairs;

(3) Equip areas with tables, chairs, eating utensils, and dishes designed to

meet the developmental needs of each client;

(4) Supervise and staff dining rooms adequately to direct self-help dining procedure, to assure that each client receives enough food and to assure that each client eats in a manner consistent with his or her developmental level: and

(5) Ensure that each client eats in an upright position, unless otherwise specified by the interdisciplinary team or a physician.

PART 485—CONDITIONS OF PARTICIPATION AND CONDITIONS FOR COVERAGE: SPECIALIZED PROVIDERS

Subpart A—[Reserved]

Subpart B—Conditions of Participation: Comprehensive Outpatient Rehabilitation Facilities

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AUTHORITY: Secs. 1102, 1138, 1861(aa), and (cc) and 1871 of the Social Security Act; (42 U.S.C. 1302, 1320b-8, 1395x and 1395hh).

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Subpart A—[Reserved]

Subpart B—Conditions of Participation: Comprehensive Outpatient Rehabilitation Facilities

§ 485.50 Basis and scope.

This subpart sets forth the conditions that facilities must meet to be certified as comprehensive outpatient rehabilitation facilities (CORFs) under section 1861(cc)(2) of the Social Security Act and be accepted for participation in Medicare in accordance with Part 489 of this chapter.

§ 485.51 Definition.

As used in this subpart, unless the context indicates otherwise, *"comprehensive outpatient rehabilitation facility", "CORF"*, or *"facility"* means a nonresidential facility that—

(a) Is established and operated exclusively for the purpose of providing diagnostic, therapeutic, and restorative services to outpatients for the rehabilitation of injured, disabled, or sick persons, at a single fixed location, by or under the supervision of a physician; and

(b) Meets all the requirements of this subpart.

§ 485.54 Condition of participation: Compliance with State and local laws.

The facility and all personnel who provide services must be in compliance with applicable State and local laws and regulations.

(a) *Standard: Licensure of facility.* If State or local law provides for licensing, the facility must be currently licensed or approved as meeting the standards established for licensure.

(b) *Standard: Licensure of personnel.* Personnel that provide service must be licensed, certified, or registered in accordance with applicable State and local laws.

§ 485.56 Condition of participation: Governing body and administration.

The facility must have a governing body that assumes full legal responsibility for establishing and implementing policies regarding the management and operation of the facility.

(a) *Standard: Disclosure of ownership.* The facility must comply with the provisions of Part 420, Subpart C of this chapter that require health care providers and fiscal agents to disclose certain information about ownership and control.

(b) *Standard: Administrator.* The governing body must appoint an administrator who—

(1) Is responsible for the overall management of the facility under the authority delegated by the governing body;

(2) Implements and enforces the facility's policies and procedures;

(3) Designates, in writing, an individual who, in the absence of the administrator, acts on behalf of the administrator; and

(4) Retains professional and administrative responsibility for all personnel providing facility services.

(c) *Standard: Group of professional personnel.* The facility must have a group of professional personnel associated with the facility that—

(1) Develops and periodically reviews policies to govern the services provided by the facility; and

(2) Consists of at least one physician and one professional representing each of the services provided by the facility.

(d) *Standard: Institutional budget plan.* The facility must have an institutional budget plan that meets the following conditions:

(1) It is prepared, under the direction of the governing body, by a committee consisting of representatives of the governing body and the administrative staff.

(2) It provides for—

(i) An annual operating budget prepared according to generally accepted accounting principles;

(ii) A 3-year capital expenditure plan if expenditures in excess of $100,000 are anticipated, for that period, for the acquisition of land; the improvement of land, buildings, and equipment; and the replacement, modernization, and expansion of buildings and equipment; and

(iii) Annual review and updating by the governing body.

(e) *Standard: Patient care policies.* The facility must have written patient care policies that govern the services it furnishes. The patient care policies must include the following:

(1) A description of the services the facility furnishes through employees and those furnished under arrangements.

(2) Rules for and personnel responsibilities in handling medical emergencies.

(3) Rules for the storage, handling, and administration of drugs and biologicals.

(4) Criteria for patient admission, continuing care, and discharge.

(5) Procedures for preparing and maintaining clinical records on all patients.

(6) A procedure for explaining to the patient and the patient's family the extent and purpose of the services to be provided.

(7) A procedure to assist the referring physician in locating another level of care for—patients whose treatment has terminated and who are discharged.

(8) A requirement that patients accepted by the facility must be under the care of a physician.

(9) A requirement that there be a plan of treatment established by a physician for each patient.

(10) A procedure to ensure that the group of professional personnel reviews and takes appropriate action on recommendations from the utilization review committee regarding patient care policies.

(f) *Standard: Delegation of authority.* The responsibility for overall administration, management, and operation must be retained by the facility itself and not delegated to others.

(1) The facility may enter into a contract for purposes of assistance in financial management and may delegate to others the following and similar services:

(i) Bookkeeping.

(ii) Assistance in the development of procedures for billing and accounting systems.

(iii) Assistance in the development of an operating budget.

(iv) Purchase of supplies in bulk form.

(v) The preparation of financial statements.

(2) When the services listed in paragraph (f)(1) of this section are delegated, a contract must be in effect and:

(i) May not be for a term of more than 5 years;

(ii) Must be subject to termination within 60 days of written notice by either party;

(iii) Must contain a clause requiring renegotiation of any provision that HCFA finds to be in contravention to any new, revised or amended Federal regulation or law;

(iv) Must state that only the facility may bill the Medicare program; and

(v) May not include clauses that state or imply that the contractor has power and authority to act on behalf of the facility, or clauses that give the contractor rights, duties, discretions, or responsibilities that enable it to dictate the administration, mangement, or operations of the facility.

§ 485.58 Condition of participation: Comprehensive rehabilitation program.

The facility must provide a coordinated rehabilitation program that includes, at a minimum, physicians' services, physical therapy services, and social or psychological services. The services must be furnished by personnel that meet the qualifications set forth in § 485.70 and must be consistent with the plan of treatment and the results of comprehensive patient assessments.

(a) *Standard: Physician services.* (1) A facility physician must be present in the facility for a sufficient time to—

(i) Provide, in accordance with accepted principles of medical practice, medical direction, medical care services, and consultation;

(ii) Establish the plan of treatment in cases where a plan has not been established by the referring physician;

(iii) Assist in establishing and implementing the facility's patient care policies; and

(iv) Participate in plan of treatment reviews, patient case review conferences, comprehensive patient assessment and reassessments, and utilization review.

(2) The facility must provide for emergency physician services during the facility operating hours.

(b) *Standard: Plan of treatment.* For each patient, a physician must establish a plan of treatment before the facility initiates treatment. The plan of treatment must meet the following requirements:

(1) It must delineate anticipated goals and specify the type, amount, frequency and duration of services to be provided.

(2) It must be promptly evaluated after changes in the patient's condition and revised when necessary.

(3) It must, if appropriate, be developed in consultation with the facility physician and the appropriate facility professional personnel.

(4) It must be reviewed at least every 60 days by a facility physician who, when appropriate, consults with the professional personnel providing services. The results of this review must be communicated to the patient's referring physician for concurrence before treatment is continued or discontinued.

(5) It must be revised if the comprehensive reassessment of the patient's status or the results of the patient case review conference indicate the need for revision.

(c) *Standard: Coordination of services.* The facility must designate, in writing, a qualified professional to ensure that professional personnel coordinate their related activities and exchange information about each patient under their care. Mechanisms to assist in the coordination of services must include—

(1) Providing to all personnel associated with the facility, a schedule indicating the frequency and type of services provided at the facility;

(2) A procedure for communicating to all patient care personnel pertinent information concerning significant changes in the patient's status;

(3) Periodic clinical record entries, noting at least the patient's status in relationship to goal attainment; and

(4) Scheduling patient case review conferences for purposes of determining appropriateness of treatment, when indicated by the results of the initial comprehensive patient assessment, reassessment(s), the recommendation of the facility physician (or other physician who established the plan of treatment), or upon the recommendation of one of the professionals providing services.

(d) *Standard: Provision of services.* (1) All patients must be referred to the facility by a physician who provides the following information to the facility before treatment is initiated:

(i) The patient's significant medical history.

(ii) Current medical findings.

(iii) Diagnosis(es) and contraindications to any treatment modality.

(iv) Rehabilitation goals, if determined.

(2) Services may be provided by facility employees or by others under arrangements made by the facility.

(3) The facility must have on its premises the necessary equipment to implement the plan of treatment and sufficient space to allow adequate care.

(4) The services must be furnished by personnel that meet the qualifications of § 485.70 and the number of qualified personnel must be adequate for the volume and diversity of services offered. Personnel that do not meet the qualifications specified in § 485.70 may be used by the facility in assisting qualified staff. When a qualified individual is assisted by these personnel, the qualified individual must be on the premises, and must instruct these personnel in appropriate patient care service techniques and retain responsibility for their activities.

(5) A qualified professional must initiate and coordinate the appropriate portions of the plan of treatment, monitor the patient's progress, and recommend changes, in the plan, if necessary.

(6) A qualified professional representing each service made available at the facility must be either on the premises of the facility or must be available through direct telecommunication for consultation and assistance during the facility's operating hours. At least one qualified professional must be on the premises during the facility's operating hours.

(7) All services must be provided consistent with accepted professional standards and practice.

(e) *Standard: Scope and site of services.* The facility must provide all the CORF services required in the plan of treatment, with the exception of one home visit to evaluate the potential impact of the home environment on the rehabilitation goals, must provide the services on its premises.

(f) *Standard: Patient assessment.* Each qualified professional involved in the patient's care, as specified in the plan of treatment, must—

(1) Carry out an initial patient assessment; and

(2) In order to identify whether or not the current plan of treatment is appropriate, perform a patient reassessment after significant changes in the patient's status.

§ 485.60 Condition of participation: Clinical records.

The facility must maintain clinical records on all patients in accordance with accepted professional standards and practice. The clinical records must be completely, promptly, and accurately documented, readily accessible, and systematically organized to facilitate retrieval and compilation of information.

(a) *Standard: Content.* Each clinical record must contain sufficient information to identify the patient clearly and to justify the diagnosis and treatment. Entries in the clinical record must be made as frequently as is necessary to insure effective treatment and must be signed by personnel providing services. All entries made by assistant level personnel must be countersigned by the corresponding professional. Documentation on each patient must be consolidated into one clinical record that must contain—

(1) The initial assessment and subsequent reassessments of the patient's needs;

(2) Current plan of treatment;

(3) Identification data and consent or authorization forms;

(4) Pertinent medical history, past and present;

(5) A report of pertinent physical examinations if any;

(6) Progress notes or other documentation that reflect patient reaction to treatment, tests, or injury, or the need to change the established plan of treatment; and

(7) Upon discharge, a discharge summary including patient status relative to goal achievement, prognosis, and future treatment considerations.

(b) *Standard: Protection of clinical record information.* The facility must safeguard clinical record information against loss, destruction, or unauthorized use. The facility must have procedures that govern the use and removal of records and the conditions for release of information. The facility must obtain the patient's written consent before releasing information not required to be released by law.

(c) *Standard: Retention and preservation.* The facility must retain clinical record information for 5 years after patient discharge and must make provision for the maintenance of such records in the event that it is no longer able to treat patients.

§ 485.62 Condition of participation: Physical environment.

The facility must provide a physical environment that protects the health and safety or patients, personnel, and the public.

(a) *Standard: Safety and comfort of patients.* The physical premises of the facility and those areas of its surrounding physical structure that are used by the patients (including at least all stairwells, corridors and passageways) must meet the following requirements:

(1) Applicable Federal, State, and local building, fire, and safety codes must be met.

(2) Fire extinguishers must be easily accessible and fire regulations must be prominently posted.

(3) A fire alarm system with local (in-house) capability must be functional, and where power is generated by electricity, an alternate power source with automatic triggering must be present.

(4) Lights, supported by an emergency power source, must be placed at exits.

(5) A sufficient number of staff to evacuate patients during a disaster must be on the premises of the facility whenever patients are being treated.

(6) Lighting must be sufficient to carry out services safely; room temperature must be maintained at comfortable levels; and ventilation through windows, mechanical means, or a combination of both must be provided.

(7) Safe and sufficient space must be available for the scope of services offered.

(b) *Standard: Sanitary environment.* The facility must maintain a sanitary environment and establish a program to identify, investigate, prevent, and control the cause of patient infections.

(1) The facility must establish written policies and procedures designed to control and prevent infection in the facility and to investigate and identify possible causes of infection.

(2) The facility must monitor the infection control program to ensure that the staff implement the policies and procedures and that the policies and procedures are consistent with current practices in the field.

(3) The facility must make available at all times a quantity of laundered linen adequate for proper care and comfort of patients. Linens must be handled, stored, and processed in a mannner that prevents the spread of infection.

(4) Provisions must be in effect to ensure that the facility's premises are maintained free of rodent and insect infestation.

(c) *Standard: Maintenance of equipment, physical location, and grounds.* The facility must establish a written preventive maintenance program to ensure that—

(1) All equipment is properly maintained and equipment needing periodic calibration is calibrated consistent with the manufacturer's recommendations; and

(2) The interior of the facility, the exterior of the physical structure housing the facility, and the exterior walkways and parking areas are clean and orderly and maintained free of

any defects that are a hazard to patients, personnel, and the public.

(d) *Standard: Access for the physically impaired.* The facility must ensure the following:

(1) Doorways, stairwells, corridors, and passageways used by patients are—

(i) Of adequate width to allow for easy movement of all patients (including those on stretchers or in wheelchairs); and

(ii) In the case of stairwells, equipped with firmly attached handrails on at least one side.

(2) At least one toilet facility is accessible and constructed to allow utilization by ambulatory and nonambulatory individuals.

(3) At least one entrance is usable by individuals in wheelchairs.

(4) In multi-story buildings, elevators are accessible to and usable by the physically impaired on the level that they use to enter the building and all levels normally used by the patients of the facility.

(5) Parking spaces are large enough and close enough to the facility to allow safe access by the physically impaired.

§ 485.64 Condition of participation: Disaster procedures.

The facility must have written policies and procedures that specifically define the handling of patients, personnel, records, and the public during disasters. All personnel associated with the facility must be knowledgeable with respect to these procedures, be trained in their application, and be assigned specific responsibilities.

(a) *Standard: Disaster plan.* The facility's written disaster plan must be developed and maintained with assistance of qualified fire, safety, and other appropriate experts. The plan must include—

(1) Procedures for prompt transfer of casualties and records;

(2) Procedures for notifying community emergency personnel (for example, fire department, ambulance, etc.);

(3) Instructions regarding the location and use of alarm systems and signals and fire fighting equipment; and

(4) Specification of evacuation routes and procedures for leaving the facility.

(b) *Standard: Drills and staff training.* (1) The facility must provide ongoing training and drills for all personnel associated with the facility in all aspects of disaster preparedness.

(2) All new personnel must be oriented and assigned specific responsibilities regarding the facility's disaster plan within two weeks of their first workday.

§ 485.66 Condition of participation: Utilization review plan.

The facility must have in effect a written utilization review plan that is implemented at least each quarter, to assess the necessity of services and promotes the most efficient use of services provided by the facility.

(a) *Standard: Utilization review committee.* The utilization review committee, consisting of the group of professional personnel specified in § 485.56(c), a committee of this group, or a group of similar composition, comprised by professional personnel not associated with the facility, must carry out the utilization review plan.

(b) *Standard: Utilization review plan.* The utilization review plan must contain written procedures for evaluating—

(1) Admissions, continued care, and discharges using, at a minimum, the criteria established in the patient care policies;

(2) The applicability of the plan of treatment to established goals; and

(3) The adequacy of clinical records with regard to—

(i) Assessing the quality of services provided; and

(ii) Determining whether the facility's policies and clinical practices are compatible and promote appropriate and efficient utilization of services.

§ 485.70 Personnel qualifications.

This section sets forth the qualifications that must be met, as a condition of participation, under § 485.58, and as a condition of coverage of services under § 410.100 of this chapter.

(a) A facility physician must be a doctor of medicine or osteopathy who—

(1) Is licensed under State law to practice medicine or surgery; and

(2) Has had, subsequent to completing a 1-year hospital internship, at least 1 year of training in the medical management of patients requiring rehabilitation services; or

(3) Has had at least 1 year of full-time or part-time experience in a rehabilitation setting providing physicians' services similar to those required in this subpart.

(b) A licensed practical nurse must be licensed as a practical or vocational nurse by the State in which practicing, if applicable.

(c) An occupational therapist and an occupational therapist assistant must meet the qualifications set forth in § 405.1202(f) and (g) of this chapter.

(d) An orthotist must—

(1) Be licensed by the State in which practicing, if applicable;

(2) Have successfully completed a training program in orthotics that is jointly recognized by the American Council on Education and the American Board for Certification in Orthotics and Prosthetics; and

(3) Be eligible to take that Board's certification examination in orthotics.

(e) A *physical therapist* and a *physical therapist assistant* must meet the qualifications set forth in § 405.1702 (d) and (e) of this chapter.

(f) A *prosthetist* must—

(1) Be licensed by the State in which practicing, if applicable;

(2) Have successfully completed a training program in prosthetics that is jointly recognized by the American Council on Education and the American Board for Certification in Orthotics and Prosthetics; and

(3) Be eligible to take that Board's certification examination in prosthetics.

(g) A *psychologist* must be certified or licensed by the State in which he or she is practicing, if that State requires certification or licensing, and must hold a masters degree in psychology from and educational institution approved by the State in which the institution is located.

(h) A *registered nurse* must be a graduate of an approved school of nursing and be licensed as a registered nurse by the State in which practicing, if applicable.

(i) A *rehabilitation counselor* must—

(1) Be licensed by the State in which practicing, if applicable;

(2) Hold at least a bachelor's degree; and

(3) Be eligible to take the certification examination administered by the Commission on Rehabilitation Counselor Certification.

(j) A *respiratory therapist* must—

(1) Be licensed by the State in which practicing, if applicable;

(2) Have successfully completed a training program accredited by the Committee on Allied Health Education and Accreditation (CAHEA) in collaboration with the Joint Review Committee for Respiratory Therapy Education; and

(3) Either—

(i) Be eligible to take the registry examination for respiratory therapists administered by the National Board for Respiratory Therapy, Inc.; or

(ii) Have equivalent training and experience as determined by the National Board for Respiratory Therapy, Inc.

(k) A *respiratory therapy technician* must—

(1) Be licensed by the State in which practicing, if applicable;

(2) Have successfully completed a training program accredited by the Committees on Allied Health Education and Accreditation (CAHEA) in collaboration with the Joint Review Committee for Respiratory Therapy Education; and

(3) Either—

(i) Be eligible to take the certification examination for respiratory therapy technicians administered by the National Board for Respiratory Therapy, Inc.; or

(ii) Have equivalent training and experience as determined by the National Board for Respiratory Therapy, Inc.

(l) A *social worker* must—

(1) Be licensed by the State in which practicing, if applicable;

(2) Hold at least a bachelor's degree from a school accredited or approved by the Council on Social Work Education; and

(3) Have 1 year of social work experience in a health care setting.

(m) A *speech-language pathologist* must meet the qualifications set forth in § 405.1702(j) of this chapter.

[48 FR 56293, Dec. 15, 1982. Redesignated and amended at 50 FR 33034, Aug. 16, 1985; 51 FR 41352, Nov. 14, 1986]

§ 485.74 Appeal rights.

The appeal provisions set forth in Part 498 of this chapter, for providers, are applicable to any entity that is participating or seeks to participate in the Medicare program as a CORF.

[48 FR 56293, Dec. 15, 1982, as amended at 52 FR 22454, June 12, 1987]

Subpart C—[Reserved]

Subpart D—Conditions for Coverage: Organ Procurement Organizations

SOURCE: 53 FR 6549, March 1, 1988, unless otherwise noted.

§ 485.301 Basis and scope.

The subpart sets forth the qualifications and requirements an organ procurement organization (OPO) must meet in order for the costs of its services in procuring organs for hospitals and transplant centers to be reimbursable under Medicare and Medicaid. Its statutory basis is section 1138(b) of the Act, as added by section 9318 of Pub. L. 99-509.

§ 485.302 Definitions.

As used in this subpart, the following definitions apply:

Entire standard metropolitan statistical area means a metropolitan statistical area, a consolidated metropolitan statistical area, or a primary statistical area listed in the State and Metropolitan Area Data Book published by the U.S. Bureau of the Census.

Organ means a human kidney, liver, heart, lung, or pancreas.

Organ procurement organization means an organization that performs or coordinates the performance of retrieving, preserving and transporting organs and maintains a system of locating prospective recipients for available organs.

Potential donor means a person who dies in circumstances (causes and conditions of death, and age at death) that are generally acceptable for donation of at least one solid organ if the donor can be identified timely and permission for donation can be obtained.

Service area means a geographical area of sufficient size that (unless the service area comprises an entire State) includes at least 2.5 million in population or at least fifty potential organ donors each year and that either includes an entire standard metropolitan statistical area or does not include any part of such an area.

Transplant center means a hospital certified by Medicare to furnish directly, for a specific organ(s), transplant and other medical and surgical specialty services required for the care of transplant patients.

§ 485.303 Condition: Organ procurement organization qualifications—General.

(a) Payment may be made under the Medicare and Medicaid programs for organ procurement costs attributable to payments made by an OPO only if the organization has been designated by the Secretary as an OPO, payment to which may be treated as organ procurement costs for reimbursement of hospitals under Medicare and Medicaid.

(b) To be initially designated as an OPO, an organization must:

(1) Apply to HCFA in writing using the application form prescribed by HCFA; and

(2) Meet the requirements in §§ 485.304 and 485.305.

(c) Upon designation, an OPO is certified for two years. To continue to be designated as the designated OPO as specified in paragraph (b) of this section, the OPO must be recertified by the Secretary at least every two years as meeting the performance standards in § 485.306 of this subpart and must continue to meet the requirements in §§ 485.304 and 485.305 of the subpart.

§ 485.304 Condition: Qualifications required of an organization for it to be a designated organ procurement organization.

To be designated by the Secretary as the OPO for its service area in accordance with § 485.303 of this subpart, an organization must at the time of application and throughout the period of its designation—

(a) Be a nonprofit entity that is exempt from Federal income taxation under section 501 of the Internal Revenue Code of 1986;

(b) Have accounting and other fiscal procedures necessary to assure the fiscal stability of the organization, including procedures to obtain payment for kidneys and non-renal organs provided to transplant centers;

(c) Have an agreement with the Secretary to be reimbursed under Medicare for the procurement of covered organs;

(d) Make available to HCFA documentation of its service area. An OPO in a service area of less than 2.5 million in population must provide to HCFA quantifiable data showing that the area yields 50 or more potential donors of solid or vascular organs per year. Documentation that precisely defines the proposed service area includes the following:

(1) The names of the counties (or parishes in Louisiana) served unless the service area includes an entire State, in which case only the name of the State must be included;

(2) Geographic boundaries of the service area for which U.S. population statistics are available;

(3) Total population in service area; and

(4) The number of and the names of acute care hospitals in the service area with an operating room and the equipment and personnel to retrieve organs;

(e) Have a director and such other staff, including an organ donation coordinator and an organ procurement specialist, necessary to obtain organs effectively from donors in its service area;

(f) Have a board of directors or an advisory board that has the authority to recommend policies relating to the donation, procurement, and distribution of organs. The board of directors or advisory board must include—

(1) Members who represent hospital administrators, tissue banks, voluntary health associations in its service area and either intensive care or emergency room personnel;

(2) Members who represent the public residing in that area;

(3) A physician with knowledge, experience, or skills in the field of human histocompatability;

(4) A neurosurgeon or another physician with knowledge or skills in the field of neurology; and

(5) A transplant surgeon from each transplant center in its service area with which the OPO has arrangements to coordinate its activities;

(g) To identify potential organ donors, have documented evidence that—(1) It has a working relationship with at least 75 percent of the hospitals that participate in the Medicare and Medicaid programs in its service area and that have an operating room and the equipment and personnel for retrieving organs; and

(2) It conducts systematic efforts intended to acquire all usable organs from potential donors;

(h) Arrange for the appropriate tissue typing of donated organs;

(i) Have a system to allocate donated organs among transplant centers and patients according to established medical criteria;

(j) Provide or arrange for the transportation of donated organs to transplant centers;

(k) Have arrangements to coordinate its activities with transplant centers in the area;

(l) Have arrangements to cooperate with tissue banks for the retrieval, processing, preservation, storage and distribution of tissues as may be appropriate to assure that all usable tissues are obtained from potential donors;

(m) Maintain and make available upon request of the Secretary, the Comptroller General, or their designees data that relate to the performance standards;

(n) Maintain data in a format that can be readily used by a successor OPO and agree to turn over to the Secretary copies of all records and data necessary to assure uninterrupted service by a successor OPO newly designated by HCFA;

(o) Have a procedure for ensuring the confidentiality of patient records. Information from or copies of records may be released only to authorized individuals and the OPO must ensure that unauthorized individuals cannot gain access to or alter patient records. Original medical records may be released by the OPO only in accordance with Federal or State laws, court orders, or subpoenas; and

(p) Conduct and participate in professional education concerning organ procurement.

[53 FR 6550, March 1, 1988; 53 FR 9172, March 21, 1988; 53 FR 18987, May 26, 1988]

§ 485.305 Condition: Organ Procurement and Transplantation Network participation.

In order to be designated as the OPO for its service area, and to continue to be the designated OPO once designated, an OPO must be a member of, have a written agreement with, and abide by the rules and requirements of the Organ Procurement and Transplantation Network established in accordance with section 372 of the Public Health Service Act.

[53 FR 6551, March 1, 1988; 53 FR 18987, May 26, 1988]

§ 485.306 Condition: Performance standards for organ procurement organizations.

(a) HCFA will not recertify any OPO that fails to meet the following performance standards:

(1) Each OPO must procure within its service area a minimum ratio of 23 cadaveric kidneys per million population of its service area for each 12 month period surveyed.

(2) Each OPO must provide a minimum ratio of cadaveric kidneys procured in its service area *and transplanted* (either locally or exported and transplanted) of 19 cadaveric kidneys per million population of its service area for each 12 month period surveyed.

(3) Each OPO must enter into a working relationship with any hospital or transplant center in the OPO's service area that requests a working relationship.

(b) An OPO designated by HCFA for its service area will be exempt from meeting these performance standards for two years after initially being designated as an OPO under § 485.303 of this subpart.

[53 FR 6551, March 1, 1988; 53 FR 9172, March 21, 1988; 53 FR 18987, May 26, 1988]

§ 485.307 Failure to meet requirements.

(a) Failure to continue to meet any of the requirements in §§ 485.304 and 485.305 of the subpart or to meet the performance standards in § 485.306(a) of this subpart (after two years after designation (see § 485.306(b) of this subpart)) may result in suspension of payment for costs for OPO services. HCFA will notify the OPO of its determination that the OPO has not met one or more of the requirements and provide a reasonable opportunity for correction. Continued failure to meet a requirement may result in termination of the OPO's agreement with the Secretary.

(b) An OPO whose payment is suspended or whose agreement with the Secretary is terminated may appeal the action in accordance with Part 498 of this chapter.

§ 485.308 Designation of one OPO for each service area.

(a) The Secretary may designate only one OPO per service area. If more than one organization applies and substantially meets the requirements of § 485.304 of this subpart in a given service area, the Secretary will consider other factors in reaching a decision concerning which organization to designate. These factors are as follows:

(1) Prior performance, including the previous year's experience in terms of the number of organs retrieved and wasted and the average cost per organ;

(2) Actual number of donors compared to the number of potential donors;

(3) The nature of relationships and degree of involvement with hospitals in the organization's service area;

(4) Bed capacity associated with the hospitals with which the organizations have a working relationship;

(5) Willingness and ability to place organs within the service area; and

(6) Proximity of the organization to the donor hospitals.

(b) An organization that applies to HCFA to be the designated OPO for its service area and that is not designated may appeal its nondesignation under Part 498 of this chapter.

PART 488—SURVEY AND CERTIFICATION PROCEDURES

Subpart A—General Provisions

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488.110 Procedural guidelines.
488.115 Care guidelines.

AUTHORITY: Secs. 1102, 1814, 1861, 1865, 1866, 1871, 1880, 1881 and 1883 of the Social Security Act (42 U.S.C. 1302, 1395f, 1395x, 1395bb, 1395cc, 1395hh, 1395qq, 1395rr and 1395tt).

SOURCE: At 53 FR 22859, June 17, 1988, unless otherwise noted.

Subpart A—General Provisions

§ 488.1 Definitions.

As used in this part—

Accredited hospital means a hospital accredited by the Joint Commission on Accreditation of Healthcare Organizations or by the American Osteopathic Association.

Act means the Social Security Act.

AOA stands for the American Osteopathic Association.

Certification is a recommendation made by the State survey agency on the compliance of providers and suppliers with the conditions of participation and conditions of coverage.

Full review means a survey of a hospital for compliance with all conditions of participation for hospitals.

JCAHO stands for the Joint Commission on Accreditation of Healthcare Organizations.

Provider of services or *provider* means a hospital, skilled nursing facility, home health agency, hospice, comprehensive outpatient rehabilitation facility, or provider of outpatient physical therapy or speech pathology services.

State includes the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, and American Samoa.

State survey agency means the State health agency or other appropriate State or local agency used by HFCA to perform survey and review functions for Medicare.

Substantial allegation means a complaint which reflects on the health and safety of patients and raises doubts as to a hospital's compliance with the conditions of participation.

Supplier means any of the following: independent laboratory; portable X-ray services; physical therapist in independent practice; ESRD facility; rural health clinic; or chiropractor.

§ 488.3 Conditions of participation; Conditions for coverage.

(a) *Basic rules.* In order to be approved for participation in or coverage under the Medicare program, a prospective provider or supplier must:

(1) Meet the applicable statutory definition in section 1861 or section 1881 of the Act; and

(2) Be in compliance with the applicable conditions prescribed in Subpart K, L, M, N, Q, or U of Part 405, Subpart C of Part 418, Part 482, or Subpart A of Part 491 of this chapter.

(b) *Special Conditions.* (1) The Secretary, after consultation with the JCAHO or AOA, may issue conditions of participation for hospitals higher or more precise than those of either those accrediting bodies.

(2) The Secretary may, at a State's request, approve health and safety requirements for providers and suppliers in that State, which are higher than those otherwise applied in the Medicare program.

(3) If a State or political subdivision imposes higher requirements on institutions as a condition for the purchase of health services under a State Medicaid Plan approved under Title XIX of the Act, (or if Guam, Puerto Rico, or the Virgin Islands does so under a State plan for Old Age Assistance under Title I of the Act, or for Aid to the Aged, Blind, and Disabled under the original Title XVI of the Act), the Secretary is required to impose similar requirements as a condition for payment under Medicare in that State or political subdivision.

§ 488.5 Effect of JCAHO or AOA accreditation.

Institutions accredited as hospitals by the JCAHO or AOA are deemed to meet all of the Medicare conditions of participation for hospitals, except:

(a) The requirement for utilization review as specified in section 1861(e)(6) of the Act and in § 482.30 of this chapter.

(b) The additional special staffing and medical records requirements that are considered necessary for the provision of active treatment in psychiatric hospitals (section 1861(f) of the Act) and implementing regulations; and

(c) Any requirement under section 1861(e) of the Act and implementing regulations which the Secretary, after consulting with JCAHO or AOA, identifies as being higher or more precise than the requirements for accreditation (section 1865(a)(4) of the Act).

§ 488.6 Validation survey.

(a) *Basis for survey.* HCFA may require a survey of an accredited hospital to validate the JCAHO or AOA accreditation process. These surveys will be conducted on a selective-sample basis, or in response to substantial allegations of significant deficiencies.

(b) *Effect of selection for survey.* A hospital selected for a validation survey must: (1) Authorize its accrediting body to release to HCFA or the State survey agency (on a confidential basis for JCAHO hospitals), a copy of the hospital's current accreditation survey. (For the rules on confidentiality, see 42 CFR 401.126:

(2) Authorize carrying out the validation survey; and

(3) Authorize its accrediting body to release periodic status reports to HCFA on correction of deficiencies when HCFA and the accrediting body agree that the latter will monitor the correction deficiences.

(c) *Refusal to cooperate with survey.* If a hospital selected for a validation survey fails to comply with the requirements specified in paragraph (b) of this section, it will no longer be deemed to meet the Medicare conditions of participation but will be subject to full review by the State survey agency in accordance with § 488.11 and may be subject to termination of its provider agreement under § 489.53 of this chapter.

(d) *Consequences of finding of noncompliance.* (1) If a validation survey results in a finding that the hospital is out of compliance with one or more conditions of participation and a significant deficiency is determined to exist, the hospital will no longer be deemed to meet the conditions of participation. Specifically, the hospital will be subject to the requirements applied to unaccredited hospitals that are found out of compliance following a State agency survey under § 488.28, and to full review by a State agency survey in accordance with § 488.11.

(2) A significant deficiency will be determined not to exist if:

(i) The accrediting body accepts the State survey agency finding of deficiencies and agrees to monitor the correction of the deficiencies in accordance with specified time frames; and

(ii) The State survey agency is unable to justify to HCFA the need for continued full review by the State survey agency to assure correction of deficiencies; and

(iii) The accrediting body provides HCFA with periodic reports of progress toward corrections.

(e) *Reinstating effect of accreditation.* An accredited hospital will be once again deemed to meet the Medicare conditions of participation in accordance with this section if:

(1) It withdraws any prior refusal to authorize its accrediting body to release a copy of the hospital's current accreditation survey;

(2) It withdraws any prior refusal to allow a validation survey;

(3) It withdraws any prior refusal to authorize its accrediting body to release periodic status reports on correction progress; and

(4) HCFA finds that the hospital meets all the Medicare conditions of participation.

(f) *Informal administrative review.* (1) An accredited hospital which is dissatisfied with a finding that it is not in compliance with a condition of participation, or a finding that it is no longer deemed to meet the conditions of participation, is entitled to an informal administrative review.

(2) The hospital must request informal review in writing within 15 days of the date it received HCFA's notice of the finding.

(3) The request should state why the finding is considered incorrect and should be accompanied by any supporting evidence and arguments.

§ 488.8 Civil rights requirements.

Providers must meet the requirements of:

(a) Title VI of the Civil Rights act of 1964, as implemented by 45 CFR Part 80, which provides that no person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or the subject to discrimination under, any program or activity receiving Federal financial assistance (section 601);

(b) Section 504 of the Rehabilitation Act of 1973, as implemented by 45 CFR Part 84, which provides that no qualified handicapped person shall, on the basis of handicap, be excluded from participation in, be denied the benefits of, or othrwise be subjected to discrimination under any program or activity receiving Federal financial assistance; and

(c) Other pertinent requirements made by the Office of Civil Rights of the Department of Health and Human Services.

§ 488.10 State survey agency review: Statutory provisions.

(a) Section 1864(a) of the Act requires the Secretary to enter into an agreement with any State that is able and willing to do so, under which appropriate State or local survey agencies will determine whether:

(1) Providers or prospective providers meet the Medicare conditions of participation;

(2) Suppliers meet the conditions for coverage; and

(3) Rural health clinics meet the conditions of certification.

(b) Section 1865(a) of the Act provides that if an institution is accredited as a hospital by the JCAHO, it will be deemed to meet the conditions of participation:

(1) Except those specified in § 488.5;

(2) Provided that such hospital, if it is included within a validation survey, authorizes the JCAHO to release to HCFA (on a confidential basis) upon request a copy of the most current JCAHO accreditation survey.

(c) Section 1864(c) of the Act authorizes the Secretary to enter into agreements with State survey agencies for the purpose of conducting validation surveys in hospitals accredited by the JCAHO. Section 1865(b) provides that an accredited hospital which is found after a validation survey to have significant deficiencies related to the health and safety of patients will no longer be deemed to meet the conditions of participation.

(d) Section 1865(a) of the Act also provides that if the Secretary finds that accreditation of an institution or agency by the AOA or any other national accreditation body provides reasonable assurance that any or all of the conditions of participation are met, the Secretary may treat such institution as meeting the conditions of participation. The Secretary has found that the accreditation of hospitals by the AOA provides such reasonable assurance, and has extended the same procedures applicable to JCAHO accredited hospitals to AOA accredited hospitals.

§ 488.11 State survey agency functions.

State and local agencies that have agreements under section 1864(a) of the Act—

(a) Survey and make recommendations regarding the issues listed in § 488.10;

(b) Conduct validation surveys as provided in § 488.6;

(c) Perform other surveys and other appropriate activities and certify their findings to HCFA; and

(d) Review statements obtained from each SNF, setting forth (from payroll records) the average numbers and types of personnel (in full-time equivalents) on each tour of duty during at least 1 week of each quarter, such week to be selected by the survey agency and to occur irregularly in each quarter of the year.

§ 488.12 Effect of survey agency certification.

Certifications by the State survey agency represent recommendations to HCFA.

(a) On the basis of these recommendations, HCFA will determine whether:

(1) A provider or supplier is eligible to participate in or be covered under the Medicare program; or

(2) An accredited hospital is deemed to meet the Medicare conditions of participation or is subject to full review by the State survey agency.

(b) Notice of HCFA's determination will be sent to the provider or supplier.

§ 488.14 Effect of PRO review.

When a PRO is conducting review activities under section 1154 of the Act and Part 466 of this chapter, its activities shall be in lieu of the utilization review and evaluation activities required of health care institutions under sections 1861(e)(6), 1861(j)(8), 1861(j)(12), and 1861(k) of the Act and will also be in lieu of survey, compliance and assistance activities required of State survey agencies under section 1864(a) with respect to those sections.

§ 488.18 Documentation of findings.

(a) The findings of the State agency with respect to each of the conditions of participation or conditions for coverage shall be adequately documented. Where the State agency certifies to the Secretary that a provider or supplier is not in compliance with the conditions, and therefore not eligible to participate in the program, such documentation includes, in addition to the description of the specific deficiencies which resulted in the agency's recommendation, a report of all consultation which has been undertaken in an effort to assist the provider or supplier to comply with the conditions, a report of the provider's or supplier's responses with respect to the consultation, and the State agency's assessment of the prospects for such improvements as to enable the provider or supplier to achieve compliance with the conditions within a reasonable period of time. (See § 488.28 of this part.)

(b) If a provider or supplier is certified by the State agency as in compliance with the conditions or as meeting the requirements for special certification (see § 488.54 of this part), with deficiencies not adversely affecting the health and safety of patients, the following information will be incorporated into the finding:

(1) A statement of the deficiencies which were found, and

(2) A description of further action which is required to remove the deficiencies, and

(3) A time-phased plan of correction developed by the provider and supplier and concurred with by the State agency, and

(4) A scheduled time for a resurvey of the institution or agency to be conducted by the State agency within 90 days following the completion of the survey.

(c) If, on the basis of the State certification, the Secretary determines that the provider or supplier is eligible to participate, the information described in paragraph (b) of this section will be incorporated into a notice of eligibility to the provider or supplier.

[39 FR 2251, Jan. 17, 1974. Redesignated at 39 FR 11419, Mar. 28, 1974, and further redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated and amended at 53 FR 23100, June 17, 1988]

§ 488.20 Periodic review of compliance and approval.

(a) Determinations by HCFA to the effect that a provider or supplier is in compliance with the conditions of participation or the conditions for coverage will be for a 12 month period, except for physical therapists in independent practice and chiropractors. Determinations for physical therapists in independent practice and chiropractors will be made as often as HCFA deems necessary and may be for more or less than a 12-month period. (See § 488.50 of this part for special rules for skilled nursing facilities.)

(b) The responsibilities of State survey agencies in the review and certification of compliance are as follows:

(1) Resurvey providers or suppliers as frequently as necessary to ascertain compliance and confirm the correction of deficiencies;

(2) Review reports prepared by a Professional Standards Review Organization (authorized under Part B Title XI of the Act) or a State inspection of care team (authorized under Title XIX of the Act) regarding the quality of a facility's care;

(3) Evaluate reports that may pertain to the health and safety of patients; and

(4) Take appropriate actions that may be necessary to achieve compliance or certify noncompliance to HCFA.

(c) A State survey agency certification to HCFA that a provider or supplier is no longer in compliance with the conditions of participation or conditions for coverage will supersede the State survey agency's previous certification.

(Secs. 1102, 1814, 1861, 1863 through 1866, 1871, and 1881; 42 U.S.C. 1302, 1395f, 1395x, 1395z through 1395cc, 1395hh, and 1395rr)

[45 FR 74833, Nov. 12, 1981. Redesignated and amended at 53 FR 23100, June 17, 1988]

§ 488.24 Certification of noncompliance.

(a) The State agency will certify that a provider or supplier is not or is no longer in compliance with the conditions of participation or conditions for coverage where the deficiencies are of such character as to substantially limit the provider's or supplier's capacity to render adequate care or which adversely affect the health and safety of patients; or

(b) If HCFA determines that an institution or agency does not qualify for participation or coverage because it is not in compliance with the conditions of participation or condition for coverage, or if a provider's agreement is terminated for that reason, the institution or agency has the right to request that the determination be reviewed. (Appeals procedures are set forth in Part 498 of this chapter.)

(Secs. 1102, 1814, 1861, 1863 through 1866, 1871, and 1881; 42 U.S.C. 1302, 1395f, 1395x, 1395z through 1395cc, 1395hh, and 1395rr)

[39 FR 2251, Jan. 17, 1974. Redesignated at 39 FR 11419, Mar. 28, 1974, and further redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 45 FR 74833, Nov. 12, 1980; 52 FR 22454, June 12, 1987. Redesignated at 53 FR 23100, June 17, 1988]

§ 488.26 Determining compliance.

(a) The decision as to whether there is compliance with a particular condition of participation or conditions for coverage will depend upon the manner and degree to which the provider or supplier satisfies the various standards within each condition. Evaluation of a provider's performance against these standards will enable the State survey agency to document the nature and extent of deficiencies, if any, with respect to a particular function, and to assess the need for improvement in relation to the prescribed conditions.

(b) The State agency must adhere to the following principles in determining compliance with participation requirements:

(1) The survey process is the means to assess compliance with Federal health, safety and quality standards;

(2) The survey process uses resident outcomes as the primary means to establish the compliance status of facilities. Specifically surveyors will directly observe the actual provision of care and services to residents, and the effects of that care, to assess whether the care provided meets the needs of individual residents;

(3) Surveyors are professionals who use their judgment, in concert with Federal forms and procedures, to determine compliance;

(4) Federal procedures are used by all surveyors to ensure uniform and consistent application and interpretation of Federal requirements;

(5) Federal forms are used by all surveyors to ensure proper recording of findings and to document the basis for the findings.

(c) The State survey agency must use the survey methods, procedures, and forms that are prescribed by HCFA.

(d) The survey agency must ensure that a facility's actual provision of care and services to residents and the effects of that care on residents are assessed in a systematic manner.

(e) A SNF survey must include the following elements:

(1) An entrance conference;

(2) A resident-centered tour of the facility;

(3) An in-depth review of a sample of residents, including observation, interview and record review;

(4) Observation of the preparation and administration of drugs for a sample of residents;

(5) Evaluation of a facility's meals, dining areas and eating assistance procedures;

(6) A description in the survey report of all deficiencies found during the survey;

(7) An exit conference; and

(8) Follow-up surveys, as appropriate.

[53 FR 23100, June 17, 1988]

§ 488.28 Providers or suppliers with deficiencies.

(a) If a provider or supplier is found to be deficient with respect to one or more of the standards in the conditions of participation or conditions for coverage, it may participate in or be covered under the Health Insurance for the Aged and Disabled Program only if the facility has submitted an acceptable plan of correction for achieving compliance within a reasonable period of time acceptable to the Secretary. The existing deficiencies noted either individually or in combination neither jeopardize the health and safety of patients nor are of such character as to seriously limit the provider's capacity to render adequate care. (See § 488.50 of this part for special requirements applicable to skilled nursing facilities.)

(b) If it is determined during a survey that a provider or supplier is not in compliance with one or more of the standards, it will be granted a reasonable time to achieve compliance. The amount of time will depend upon the nature of the deficiency and the State survey agency's judgment as to the capabilities of the facility to provide adequate and safe care. Ordinarily a provider or supplier will be expected to take the steps needed to achieve compliance within 60 days of being notified of the deficiencies but the State survey agency may recommend that additional time be granted by the Secretary in individual situations, if in its judgment it is not reasonable to expect compliance within 60 days, e.g., a facility must obtain the approval of its governing body, or engage in competitive bidding.

[39 FR 2251, Jan. 17, 1974. Redesignated at 39 FR 11419, Mar. 28, 1974, and further redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated and amended at 53 FR 23100, June 17, 1988]

Subpart B—Special Requirements

§ 488.50 Special requirements applicable to skilled nursing facilities with deficiencies.

(a) Where the facility is not in full compliance with the standards contained in Subpart K of Part 405, the period of certification shall:

(1) Be restricted to a period that is no later than the 60th day following the end of the time period specified for the correction of deficiencies in a written plan which the Secretary has approved: *Provided*, That such period shall not exceed 12 full calendar months, except as provided in §§ 489.15(d) and 489.16 of this chapter; or

(2) Provide a conditional period of 12 full months, subject to an automatic cancellation clause, the certification will expire at the close of a predetermined date which is no later than the 60th day following the end of the time period specified for the correction of deficiencies: *Provided*, That such date will occur within such 12-month period, unless the Secretary determines that all required corrections have been satisfactorily completed or that the facility has made substantial effort and progress in correcting such deficiencies and has resubmitted in writing a plan of correction acceptable to the Secretary.

(b) If the facility continues to be out of compliance with the same standard(s) at the end of the term of the agreement, a new agreement may not be accepted for filing (see § 488.20(b) of this part).

(c) When an agreement with a skilled nursing facility is not renewed at the end of its specified term (including the automatic cancellation of agreement), see §§ 489.15(d) and 489.16 of this chapter for public notice and the right to request review.

(d) If the latest survey discloses that a skilled nursing facility that had standards out of compliance during the last survey is no longer in compliance with a standard that was previously met, a new period of certification may be approved only if, in the judgment of the Secretary, the new deficiency(ies) has occurred:

(1) Despite adequately documented intensive efforts or for reasons beyond its control, the skilled nursing facility was unable to maintain compliance, and

(2) Despite the deficiency the facility is making the best use of its resources to render adequate care.

(e) If a skilled nursing facility can document to the State's satisfaction that it achieved compliance with a previously unmet standard during the period of certification but for reasons beyond its control, e.g., loss of key staff member, was found out of compliance by the time of the next survey, this may be treated as a new deficiency instead of a carry-over deficiency unless in the judgment of the Secretary the facility did not make a good faith effort to maintain compliance with the standard.

[39 FR 2251, Jan. 17, 1974. Redesignated at 39 FR 11419, Mar. 28, 1974, and further redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated and amended at 53 FR 23100, June 17, 1988]

§ 488.52 Special requirements applicable to independent laboratories.

(a) The services of a qualified independent laboratory for which reimbursement may be made under the supplementary medical insurance program relate only to diagnostic tests performed in an independent laboratory as defined in § 405.1311(a) of this chapter. Diagnostic laboratory tests for purposes of section 1861(s)(10) and (11) of the Act and for purposes of this Subparts A, B and C of this part shall include only those clinical and anatomical pathology diagnostic tests and procedures defined in § 405.1311(b) of this chapter. Diagnostic tests furnished by out-of-hospital physicians whose primary practice is directly attending patients and/or consultation as defined in § 405.1311(f) of this chapter, even though conducted partly through diagnostic procedures, are considered physicians' services rather than clinical laboratory services.

(b) A laboratory that requests an initial certification, or recertification by reason of a change in a director, but which meets all other requirements of

Subpart M of Part 405, except whose directory qualifies solely under the provisions of § 405.1312(b)(4) of this chapter, can be certified provided such laboratory requests approval based on such director's qualifications no later than 1 year following the effective date of these regulations.

(c) Independent laboratories previously found in compliance, but which have had their approval revoked in total or in a specialty or subspecialty because of unsatisfactory performance in proficiency testing, may subsequently be certified by the State agency and determined by the Secretary to be in compliance with the conditions where:

(1) After a 6-month period, an appraisal of the laboratory's performance in a proficiency testing program as defined in § 405.1311(c) of this chapter reflects satisfactory test results on at least two sets of specimens, or

(2) After a 3-month period, the State agency's assessment of the laboratory's performance in examining proficiency test samples, analyzed during at least two State agency onsite visits, establishes the laboratory's competency.

(d) A laboratory which meets the requirements of § 488.28 of this part or paragraph (c) of this section may continue to be certified by the State agency and determined by the Secretary to be in compliance with these conditions where it (1) timely reports a change in ownership, location, directors, or supervisors, or (2) permits a State agency to conduct an onsite visit or survey at any time during the laboratory's regular hours of operations.

[39 FR 2251, Jan. 17, 1974. Redesignated at 39 FR 11419, Mar. 28, 1974, and amended at 41 FR 27962, July 8, 1976. Further redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 47 FR 31531, July 20, 1982; 51 FR 22041, June 17, 1986. Redesignated and amended at 53 FR 23100, June 17, 1988]

§ 488.54 Temporary waivers applicable to hospitals.

(a) *General provisions.* If a hospital is found to be out of compliance with one or more conditions of participation for hospitals, as specified in Part 482 of this chapter, a temporary waiver may be granted by HCFA. HCFA may extend a temporary waiver only if such a waiver would not jeopardize or adversely affect the health and safety of patients. The waiver may be issued for any one year period or less under certain circumstances. The waiver may be withdrawn earlier if HCFA determines this action is necessary to protect the health and safety of patients. A waiver may be granted only if:

(1) The hospital is located in a rural area. This includes all areas not delineated as "urban" by the Bureau of the Census, based on the most recent census;

(2) The hospital has 50 or fewer inpatient hospital beds;

(3) The character and seriousness of the deficiencies do not adversely affect the health and safety of patients; and

(4) The hospital has made and continues to make a good faith effort to comply with personnel requirements consistent with any waiver.

(b) *Minimum compliance requirements.* Each case will have to be decided on its individual merits, and while the degree and extent of compliance will vary, the institution must, as a minimum, meet all of the statutory conditions in section 1861(e)(1)–(8), in addition to meeting such other requirements as the Secretary finds necessary under section 1861(e)(9). (For further information relating to the exception in section 1861(e)(5) of the Act, see paragraph (c) of this section.)

(c) *Temporary waiver of 24-hour nursing requirement of 24-hour registered nurse requirement.* HCFA may waive the requirement contained in section 1861(e)(5) that a hospital must provide 24-hour nursing service furnished or supervised by a registered nurse. Such a waiver may be granted when the following criteria are met:

(1) The hospital's failure to comply fully with the 24-hour nursing requirement is attributable to a temporary shortage of qualified nursing personnel in the area in which the hospital is located.

(2) A registered nurse is present on the premises to furnish or supervise the nursing services during at least the daytime shift, 7 days a week.

(3) The hospital has in charge, on all tours of duty not covered by a regis-

tered nurse, a licensed practical (vocational) nurse.

(4) The hospital complies with all requirements specified in paragraph (a) of this section.

(d) *Temporary waiver for technical personnel.* HCFA may waive technical personnel requirements, issued under section 1861(e)(9) of the Act, contained in the Conditions of Participation; Hospitals (Part 482 of this chapter). Such a waiver must take into account the availability of technical personnel and the educational opportunities for technical personnel in the area in which the hospital is located. HCFA may also limit the scope of services furnished by a hospital in conjunction with the waiver in order not to adversely affect the health and safety of the patients. In addition, the hospital must also comply with all requirements specified in paragraph (a) of this section.

[39 FR 2251, Jan. 17, 1974. Redesignated at 39 FR 11419, Mar. 28, 1974, and amended at 41 FR 27962, July 8, 1976. Further redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 47 FR 31531, July 20, 1982; 51 FR 22041, June 17, 1986. Redesignated at 53 FR 23100, June 17, 1988]

§ 488.56 Temporary waivers applicable to skilled nursing facilities.

(a) *Waiver of 7-day registered nurse requirement.* To the extent that § 405.1124 of this chapter requires any skilled nursing facility to engage the services of a registered nurse more than 40 hours a week, the Secretary may waive such requirement for such periods as he deems appropriate if, based upon documented findings of the State agency, he determines that:

(1) Such facility is located in a rural area and the supply of skilled nursing facility services in such area is not sufficient to meet the needs of individual patients therein,

(2) Such facility has at least one fulltime registered nurse who is regularly on duty at such facility 40 hours a week, and

(3) Such facility (i) has only patients whose attending physicians have indicated (through physicians' orders or admission notes) that each such patient does not require the services of a registered nurse for a 48-hour period, or (ii) has made arrangements for a registered nurse or a physician to spend such time at the facility as is determined necessary by the patient's attending physician to provide necessary services on days when the regular full-time registered nurse is not on duty.

(4) Such facility has made and continues to make a good faith effort to comply with the more than 40-hour registered nurse requirement, but such compliance is impeded by the unavailability of registered nurses in the area.

(b) *Waiver of medical director requirement.* To the extent that § 405.1122 of this chapter requires any skilled nursing facility to engage the services of a medical director either part-time or full-time, the Secretary may waive such requirement for such periods as he deems appropriate if, based upon documented findings of the State agency, he determines that:

(1) Such facility is located in an area where the supply of physicians is not sufficient to permit compliance with this requirement without seriously reducing the availability of physician services within the area, and

(2) Such facility has made and continues to make a good faith effort to comply with § 405.1122 of this chapter, but such compliance is impeded by the unavailability of physicians in the area.

[39 FR 35777, Oct. 3, 1974. Redesignated and amended at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 53 FR 23100, June 17, 1988]

§ 488.60 Special procedures for approving end stage renal disease facilities.

(a) *Considerations for approval.* An ESRD facility which wishes to be approved for coverage, or which wishes any expansion of dialysis services to be approved for coverage in accordance with Subpart U of Part 405, must secure the Secretary's determination thereunder. In addition to the certification by the State agency referred to in § 488.12 of this part, data furnished by network organizations and recommendations of the Public Health Service, concerning the contribution of a facility to the furnishing of end-stage renal disease services in its network and concerning the facility's compliance with professional norms and standards (see Subpart U of Part 405), shall be considered by the Secretary in determining whether to approve a facility for coverage or for any expansion of services under the End-Stage Renal Disease Program. The facility will also be required to submit data pertaining to its qualifications for approval or for any expansion of services, for consideration in the Secretary's determination.

(b) *Determining compliance with minimal utilization rates: Time limitations*—(1) *Unconditional status.* A facility which meets minimal utilization requirements will be assigned this status as long as it continues to meet these requirements.

(2) *Conditional status.* A conditional status may be granted to a facility for not more than four consecutive calendar years and will not be renewable (see § 405.2122(b) of this chapter). Its status may be examined each calendar year to ascertain its compliance with Subpart U.

(3) *Exception status.* Under unusual circumstances (see § 405.2122 (b) of this chapter) the Secretary may grant a time-limited exception to a facility which is not in compliance with the minimal utilization rate(s) for either unconditional status or conditional status. This exception status may be granted, and may be renewed on an annual basis, under circumstances where rigid application of minimal utilization rate requirements would adversely affect the achievement of ESRD program objectives.

(c) *New applicant.* A facility which has not previously participated in the ESRD program must submit a plan detailing how it expects to meet the conditional minimal utilization rate status by the end of the second calendar year of its operation under the program and meet the unconditional minimal utilization rate status by the end of the fourth calendar year of its operation under the program.

(d) *Notification.* The Secretary will notify each facility and its network coordinating council of its initial and its subsequent minimal utilization rate classification.

(e) *Failure to meet minimal utilization rate.* A facility failing to meet standards for unconditional status or conditional status, or if applicable, for exception status, will be so notified at the time of such classification.

(f) *Interim regulations participant.* A facility previously participating under the interim regulations will not be approved under the program established by Subpart U until it has demonstrated that it meets all the applicable requirements of this subpart, including the appropriate minimal utilization rate. It may continue under the interim program only for a period not to exceed 1 year from the effective date of these amendments (see § 405.2100(c) of this chapter). During this period it may demonstrate its ability to meet the appropriate minimal utilization rate. Failure to qualify under this subpart will automatically terminate coverage of such facility's services under the ESRD program at the end of such year.

[41 FR 22510, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and further amended at 45 FR 58124, Sept. 2, 1980. Redesignated and amended at 53 FR 23100, June 17, 1988]

§ 488.64 Remote facility variances for utilization review requirements.

(a) As used in this section:

(1) An "available" individual is one who:

(i) Possesses the necessary professional qualifications;

(ii) Is not precluded from participating by reason of financial interest in any such facility or direct responsibility for the care of the patients being reviewed or, in the case of a skilled nursing facility, employment by the facility; and

(iii) Is not precluded from effective participation by the distance between the facility and his residence, office, or other place of work. An individual whose residence, office, or other place of work is more than approximately one hour's travel time from the facility shall be considered precluded from effective participation.

(2) "Adjacent facility" means a health care facility located within a 50-mile radius of the facility which requests a variance.

(b) The Secretary may grant a requesting facility a variance from the time frames set forth in §§ 405.1137(d) of this chapter and 482.30 as applicable, within which reviews all of cases must be commenced and completed, upon a showing satisfactory to the Secretary that the requesting facility has been unable to meet one or more of the requirements of § 405.1137 of this chapter or § 482.30 of this chapter, as applicable, by reason of insufficient medical and other professional personnel available to conduct the utilization review required by § 405.1137 of this chapter or § 482.30 of this chapter, as applicable.

(c) The request for variance shall document the requesting facility's inability to meet the requirements for which a variance is requested and the facility's good faith efforts to comply with the requirements contained in § 405.1137 of this chapter or § 482.30 of this chapter, as applicable.

(d) The request shall include an assurance by the requesting facility that it will continue its good faith efforts to meet the requirements contained in § 405.1137 of this chapter or § 482.30 of this chapter, as applicable.

(e) A revised utilization review plan for the requesting facility shall be submitted concurrently with the request for a variance. The revised plan shall specify the methods and procedures which the requesting facility will use, if a variance is granted, to assure:

(1) That effective and timely control will be maintained over the utilization of services; and

(2) That reviews will be conducted so as to improve the quality of care provided to patients.

(f) The request for a variance shall include:

(1) The name, location, and type (e.g., hospital, skilled nursing facility) of the facility for which the variance is requested;

(2) The total number of patient admissions and average daily patient census at the facility within the previous six months;

(3) The total number of title XVIII and title XIX patient admissions and the average daily patient census of title XVIII and title XIX patients in the facility within the previous six months;

(4) As relevant to the request, the names of all physicians on the active staff of the facility and the names of all other professional personnel on the staff of the facility, or both;

(5) The name, location, and type of each adjacent facility (e.g., hospital, skilled nursing facility);

(6) The distance and average travel time between the facility and each adjacent facility;

(7) As relevant to the request, the location of practice of available physicians and the estimated number of other available professional personnel, or both (see paragraph (a)(1)(iii) of this section);

(8) Documentation by the facility of its attempt to obtain the services of available physicians or other professional personnel, or both; and

(9) A statement of whether a PRO exists in the area where the facility is located.

(g) The Secretary shall promptly notify the facility of the action taken on the request. Where a variance is in effect, the validation of utilization review pursuant to § 405.1137 of this chapter or § 482.30 shall be made with reference to the revised utilization review plan submitted with the request for variance.

(h) The Secretary, in granting a variance, will specify the period for which the variance has been granted; such period will not exceed one year. A request for a renewal shall be submitted not later than 30 days prior to the expiration of the variance and shall contain all information required by paragraphs (c), (d), and (f) of this section. Renewal of the variance will be contingent upon the facility's continuing to meet the provisions of this section.

[40 FR 30818, July 23, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977; 51 FR 22041, June 17, 1986; 51 FR 27847, Aug. 4, 1986; 51 FR 43197, Dec. 1, 1986. Redesignated and amended at 53 FR 23100, June 17, 1988]

Subpart C—Survey Forms and Procedures

§ 488.100 Long term care survey forms, Part A.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO. 0938-0400

PART A — ADMINISTRATIVE AND PROCEDURAL REQUIREMENTS

MEDICARE / MEDICAID SKILLED NURSING FACILITY AND INTERMEDIATE CARE FACILITY SURVEY REPORT

PROVIDER NUMBER	FACILITY NAME AND ADDRESS (*City, State, Zip Code*)
VENDOR NUMBER	
SURVEY DATE	
SURVEYORS' NAMES	TITLES

Form HCFA-525 (2-86)

Page 1

NAME OF FACILITY

CODE	COMPLIANCE WITH STATE AND LOCAL LAWS	YES	NO	N/A	EXPLANATORY STATEMENT
F500	**Compliance with State and Local Laws** ***(Condition of Participation)*** SNF (405.1120) ☐ MET ☐ NOT MET				
F501	A. **Licensure** SNF (405.1120(a)) (Standard) ☐ MET ☐ NOT MET				
F502	ICF (442.251) (Standard) ☐ MET ☐ NOT MET				
F503	The facility has a current State License (Number __________)				
F504	B. **Personnel Licensure** SNF (405.1120(b)) (Standard) ☐ MET ☐ NOT MET				
F505	ICF (442.302) (Standard) ☐ MET ☐ NOT MET				
F506	Staff of the facility are licensed or registered in accordance with applicable State laws.				
F507	C. **Compliance with Other Laws** SNF (405.1120(c)) (Standard) ☐ MET ☐ NOT MET				
F508	ICF (442.252) (Standard) ☐ MET ☐ NOT MET				
F509	ICF (442.315) (Standard) ☐ MET ☐ NOT MET				
F510	The facility is in compliance with applicable Federal, State and local laws and regulations relating to fire and safety, sanitation, communicable and reportable diseases, postmortem procedures and other relevant health and safety requirements.				

NAME OF FACILITY

CODE	COMPLIANCE WITH STATE AND LOCAL LAWS/ GOVERNING BODY AND MANAGEMENT	YES	NO	N/A	EXPLANATORY STATEMENT
	The facility is in compliance with applicable regulations pertaining to:				
F511	Buying, dispensing, safeguarding, administering, and disposing of medications and controlled substances. **Exception: Not applicable to SNFs.**				
F512	Construction, maintenance and equipment. **Exception: Not applicable to SNFs.**				
F513	Current reports from all responsible governmental agencies are retained at the facility.				
F514	**Governing Body and Management *(Condition of Participation)*** SNF (405.1121) ☐ MET ☐ NOT MET The facility has a governing body with full legal authority and responsibility for operation of the facility.				
F515	A. **Disclosure** SNF (405.1121(a)) (Standard) ☐ MET ☐ NOT MET Full disclosure of ownership has been made in accordance with requirements at 42 CFR 420.206.				
F516	B. **Administration** SNF (405.1121(c)) (Standard) ☐ MET ☐ NOT MET				
F517	1. Written bylaws address the operation of the facility.				
F518	2. Written bylaws and policies address effective resident care.				
F519	3. Bylaws are reviewed and revised as necessary.				

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NAME OF FACILITY

CODE	GOVERNING BODY AND MANAGEMENT	YES	NO	N/A	EXPLANATORY STATEMENT
F520	ICF (442.301) (Standard) ☐ MET ☐ NOT MET				
	C. **Independent Medical Review**				
F521	SNF (405.1121(d)) (Standard) ☐ MET ☐ NOT MET The facility has policies which ensure that the facility cooperates in an effective program for regular independent medical evaluation and audit of residents in the facility to the extent required by the programs in which the facility participates.				
	D. **Administrator**				
F522	SNF (405.1121(e)) (Standard) ☐ MET ☐ NOT MET				
F523	ICF (442.303) (Standard) ☐ MET ☐ NOT MET				
F524	The facility has a licensed administrator who has authority for the overall operation of the facility. (Administrator's license or registration number ________)				
	E. **Resident Care Director**				
F525	ICF (442.304) (Standard) ☐ MET ☐ NOT MET				
F526	1. The administrator or another professional staff member is the resident care director (RSD).				
F527	2. The RSD coordinates and monitors each resident's care.				

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NAME OF FACILITY

CODE	GOVERNING BODY AND MANAGEMENT	YES	NO	N/A	EXPLANATORY STATEMENT
	F. Institutional Planning				
F528	SNF (405.1121(f)) (Standard) ☐ MET ☐ NOT MET				
F529	1. The facility has an overall plan and budget prepared by a committee of representatives from the governing body, administrative staff, and the organized medical staff (if any).				
F530	2. The overall plan and budget is reviewed and updated at least annually.				
F531	3. The plan includes a capital expenditures plan, if necessary.				
	G. Personnel Policies and Procedures				
F532	SNF (405.1121(g)) (Standard) ☐ MET ☐ NOT MET				
	1. The facility has written policies and procedures that support sound resident care and personnel practices and address, at least:				
F533	a. Control of communicable disease.				
F534	b. The review of employee incidents and accidents to identify health and safety hazards, and				
F535	c. The existence of a safe and sanitary environment.				
F536	2. Personnel records are current, available to each employee, and contain sufficient information to support placement in the position to which assigned.				
F537	3. Referral or provision for periodic health examinations to ensure freedom from communicable disease.				

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NAME OF FACILITY

CODE	GOVERNING BODY AND MANAGEMENT	YES	NO	N/A	EXPLANATORY STATEMENT
	H. **Outside Resources/Consultant Agreements**				
F538	SNF (405.1121(i)) (Standard) ☐ MET ☐ NOT MET				
F539	ICF (442.317) (Standard) ☐ MET ☐ NOT MET				
F540	**The facility has written agreements with qualified persons to render a service (if it does not employ a qualified professional person to do so). The agreements:**				
F541	1. **Address the responsibilities, functions, objectives, and terms (including financial arrangements and charges);**				
F542	2. **Are signed by an authorized representative of the facility and the outside resource; and**				
F543	3. **Specify that the facility retains ultimate responsibility for the services rendered.**				
	I. **Notification of Change in Resident Status**				
F544	SNF (405.1121(j)) (Standard) ☐ MET ☐ NOT MET				
F545	**The facility has policies and procedures to notify physicians and other responsible persons in the event of an accident involving the resident, or resident's physical, mental or emotional status, or resident charges, billings or related administrative matter.**				

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NAME OF FACILITY

CODE	GOVERNING BODY AND MANAGEMENT	YES	NO	N/A	EXPLANATORY STATEMENT
	J. **Resident Rights**				
F546	SNF (405.1121(k)) (Standard) ☐ MET ☐ NOT MET **Indicators 1 thru 12 apply to SNFs.**				
F547	ICF (442.311) (Standard) ☐ MET ☐ NOT MET				
	1. **Information**				
F548	a. The facility informs each resident, before or at the time of admission, of his rights and responsibilities.				
F549	b. The facility informs each resident, before or at the time of admission, of all rules governing resident conduct.				
F550	c. The facility informs each resident of amendments to their policies on residents' rights and responsibilities and rules governing conduct.				
F551	d. Each resident acknowledges in writing receipt of residents' rights information and any amendment to it.				
F552	e. The resident must be informed in writing of all services and charges for services.				
F553	f. The resident must be informed in writing of all changes in services and charges before or at the time of admission and on a continuing basis.				
F554	g. The resident must be informed of services not covered by Medicare or Medicaid in the basic rate.				

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NAME OF FACILITY

CODE	GOVERNING BODY AND MANAGEMENT	YES	NO	N/A	EXPLANATORY STATEMENT
	2. **Medical Condition and Treatment**				
F555	a. Each resident is informed by a physician of his health and medical condition unless the physician decides that informing the resident is medically contraindicated.				
F556	b. Each resident is given an opportunity to participate in planning his total care and medical treatment.				
F557	c. Each resident is given an opportunity to refuse treatment.				
F558	d. Each resident gives informed, written consent before participating in experimental research.				
F559	e. If the physician decides that informing the resident of his health and medical condition is medically contraindicated, the physician has documented this decision in the resident's medical record.				
	3. **Transfer and Discharge** Each resident is transferred or discharged only for:				
F560	a. **Medical reasons.**				
F561	b. **His/her welfare** or that of other residents.				
F562	c. **Nonpayment except as prohibited by the Medicare** or Medicaid program.				
	4. **Exercising Rights**				
F563	a. **Each resident is encouraged and assisted to exercise his/her rights as a resident of the facility and as a citizen.**				
F564	b. **Each resident is allowed to submit complaints and recommendations concerning the policies and services of the facility to staff or to outside representatives of the resident's choice or both.**				
F565	c. **Such complaints are submitted free from restraint,** coercion, discrimination, or reprisal.				

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NAME OF FACILITY

CODE	GOVERNING BODY AND MANAGEMENT	YES	NO	N/A	EXPLANATORY STATEMENT
	5. **Financial Affairs**				
F566	a. **Residents are allowed** to manage their own personal financial affairs.				
F567	b. **The facility establishes** and maintains a system that assures full and complete accounting of residents' personal funds. An accounting report is made to residents in skilled nursing facilities at least on a quarterly basis.				
F568	c. **The facility does** not commingle resident funds with any other funds other than resident funds.				
F569	d. If a resident requests assistance from the facility in managing his personal financial affairs, resident's delegation is in writing.				
	e. The facility system of accounting includes written receipts for:				
F570	1. **All personal possessions** and funds received by or deposited with the facility.				
F571	2. **All disbursement** made to or for the resident.				
F572	f. The financial record must be available to the resident and his/her family.				
	6. **Freedom from Abuse and Restraints**				
F573	a. Each resident is free from mental and physical abuse				
F574	b. Chemical and physical restraints are only used when authorized by a physician in writing for a specified period of time or in emergencies.				
F575	c. If used in emergencies, they are necessary to protect the resident from injury to himself or others				

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NAME OF FACILITY

CODE	GOVERNING BODY AND MANAGEMENT	YES	NO	N/A	EXPLANATORY STATEMENT
F576	d. The use is authorized by a professional staff member identified in the written policies and procedures of the facility.				
F577	e. The use is reported promptly to the resident's physician by the staff member.				
F578	7. **Privacy** a. Each resident is treated with respect, consideration and full recognition of his/her dignity and individuality.				
F579	b. Each resident is given privacy during treatment and care of personal needs.				
F580	c. Each resident's records, including information in an automated data bank, are treated confidentially.				
F581	d. Each resident must give written consent before the facility releases information from his/her record to someone not otherwise authorized to receive it.				
F582	e. Married residents are given privacy during visits by their spouses.				
F583	f. Married residents are permitted to share a room.				
F584	8. **Work** No resident may be required to perform services for the facility.				
F585	9. **Freedom of Association and Correspondence** a. Each resident is allowed to communicate, associate and meet privately with individuals of his choice unless this infringes upon the rights of another resident.				
F586	b. Each resident is allowed to send and receive personal mail unopened.				

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NAME OF FACILITY

CODE	GOVERNING BODY AND MANAGEMENT	YES	NO	N/A	EXPLANATORY STATEMENT
	10. **Activities**				
F587	Each resident is allowed to participate in social, religious, and community group activities.				
	11. **Personal Possessions**				
F588	Each resident is allowed to retain and use his personal possessions and clothing as space permits.				
	12. **Written Policies and Procedures: Delegation of Rights and Responsibilities**				
F589	ICF (442.312) (Standard) ☐ MET ☐ NOT MET				
F590	a. The facility has written policies and procedures that provide that all the rights and responsibilities of a resident pass to the resident's guardian, next of kin or sponsoring agency or agencies if the resident is adjudicated incompetent under State law or is determined by his physician to be incapable of understanding his rights and responsibilities.				
F591	b. Physician determinations of incapability and the specific reasons thereof are recorded by the physician in the resident's record.				
	K. **Resident Care Policies**				
F592	SNF (405.1121(l)) (Standard) ☐ MET ☐ NOT MET				
F593	1. The facility has written policies to govern the continuing skilled nursing care and related medical or other services provided.				
F594	2. These policies reflect awareness of and provision for meeting the total medical and psychosocial needs of residents including admission, transfer, discharge planning, and the range of services available to residents, and				

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NAME OF FACILITY

CODE	GOVERNING BODY AND MANAGEMENT	YES	NO	N/A	EXPLANATORY STATEMENT
F595	3. The protection of residents' personal and property rights				
F596	4. The policies are developed by a group of professional personnel, including the Medical Director or the organized medical staff, and are periodically reviewed and revised (if necessary).				
F597	5. These policies are available to admitting physicians, sponsoring agencies, residents, and the public.				
F598	6. The Medical Director or a registered nurse is designated as responsible for the execution of the policies.				
F599	**L. Public Availability** ICF (442.305) (Standard) ☐ MET ☐ NOT MET				
F600	1. The facility has written policies and procedures governing all the services it provides.				
F601	2. The policies and procedures are available to the staff and residents, members of the family, the public, and legal representatives of residents.				
F602	**M. Admissions** ICF (442.306) (Standard) ☐ MET ☐ NOT MET				
	The facility has written policies and procedures that ensure that it admits as residents only those residents whose needs can be met by:				
F603	1. the facility itself.				
F604	2. the facility in cooperation with community resources.				
F605	3. the facility in cooperation with other providers of care affiliated with or under contract to the facility.				

NAME OF FACILITY

CODE	GOVERNING BODY AND MANAGEMENT	YES	NO	N/A	EXPLANATORY STATEMENT
F606	N. **Transfers** ICF (442.307) (Standard) ☐ MET ☐ NOT MET				
F607	1. The facility has written policies and procedures to ensure that residents are transferred promptly to a hospital, SNF or other appropriate facility when a change is necessary.				
F608	2. Except in emergencies, the facility consults the resident, his next of kin, the attending physician, and the responsible agency, if any, at least five days before discharge.				
F609	3. The facility uses casework services and other means to ensure that adequate arrangements are made to meet resident's needs through other resources.				
F610	O. **Restraints** ICF (442.308) (Standard) ☐ MET ☐ NOT MET				
F611	The facility has written policies and procedures that: 1. Define the uses of chemical and physical restraints.				
F612	2. Identify the professional personnel who may authorize the use of restraints in emergencies under 442.311(f).				
F613	3. Describe procedures for monitoring and controlling the use of these restraints.				
F614	P. **Complaints** ICF (442.309) (Standard) ☐ MET ☐ NOT MET				
F615	The facility has written policies and procedures that: 1. Describe the procedures the facility uses to receive complaints and recommendations from residents.				
F616	2. Ensure that the facility responds to complaints and recommendations.				

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NAME OF FACILITY

CODE	GOVERNING BODY AND MANAGEMENT	YES	NO	N/A	EXPLANATORY STATEMENT
	Q **Staff Development**				
F617	SNF (405.1121(h)) (Standard) ☐ MET ☐ NOT MET				
F618	ICF (442.314) (Standard) ☐ MET ☐ NOT MET				
F619	1. The facility conducts an orientation program for all new employees that includes a review of all its policies.				
F620	2. The facility plans and conducts an inservice staff development program for all personnel to assist them in developing and improving their skills.				
F621	3. The facility maintains a record of the orientation and staff development programs it conducts.				
F622	4. The record includes the content of the program and the names of participants.				
F623	5. Inservice training includes at least prevention and control of infections, fire prevention and safety, confidentiality of resident information, and preservation of resident dignity including protection of resident's privacy and personal and property rights.				

NAME OF FACILITY

CODE	MEDICAL DIRECTION	YES	NO	N/A	EXPLANATORY STATEMENT
	Medical Direction ***(Condition of Participation)***				
F624	SNF (405.1122) ☐ MET ☐ NOT MET The facility has a written agreement with a licensed physician to serve as Medical Director on a part-time or full-time basis as is appropriate to the needs of the residents and the facility. (See 405.1911(b) regarding waiver of this requirement.)				
	A. **Coordination of Medical Care**				
F625	SNF (405.1122(a)) (Standard) ☐ MET ☐ NOT MET				
F626	1. Medical direction and coordination of medical care in the facility are provided by a Medical Director.				
F627	2. The Medical Director is responsible for development of policies approved by the governing body.				
F628	3. Coordination of medical care includes liaison with attending physicians to ensure their writing orders promptly upon admission of a resident, and periodic evaluation of the adequacy and appropriateness of health professional and supportive staff and services.				
	B. **Responsibilities to the Facility**				
F629	SNF (405.1122(b)) (Standard) ☐ MET ☐ NOT MET				
F630	1. The Medical Director is responsible for surveillance of the health status of the facility's employees.				
F631	2. Incidents and accidents that occur on the premises are reviewed by the Medical Director to identify hazards to health and safety.				

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NAME OF FACILITY

CODE	PHYSICIAN SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	Physician Services *(Condition of Participation)*				
F632	SNF (405.1123) ☐ MET ☐ NOT MET Residents in need of skilled or rehabilitative care are admitted to the facility only upon the recommendation of, and remain under the care of, a physician. To the extent feasible, each resident designates a personal physician.				
	A. Physician Supervision				
F633	SNF (405.1123(b)) (Standard) ☐ MET ☐ NOT MET				
F634	ICF (442.346) (Standard) ☐ MET ☐ NOT MET				
F635	1. The facility has a policy that the health care of every resident must be under the supervision of a physician.				
F636	2. All attending physicians must make arrangements for the medical care of their residents in their absence.				
	B. Emergency Services				
F637	SNF (405.1123(c)) (Standard) ☐ MET ☐ NOT MET The facility has written procedures available at each nurses' station, that provide for having a physician available to furnish necessary medical care in case of emergency.				

NAME OF FACILITY

CODE	NURSING SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	Nursing Services *(Condition of Participation)*				
F638	SNF (405.1124) ☐ MET ☐ NOT MET The facility provides 24-hour service by licensed nurses, including the services of a registered nurse at least during the day tour of duty, 7 days a week. There is an organized nursing service with a sufficient number of qualified nursing personnel to meet the total nursing needs of all residents (See 405.1911(a) regarding waiver of the 7-day registered nurse requirement).				
F639	ICF (442.342) (Standard) ☐ MET ☐ NOT MET The facility provides nursing care as needed including restorative nursing care.				
	A. Director of Nursing Services				
F640	SNF (405.1124(a)) (Standard) ☐ MET ☐ NOT MET				
F641	1. The director of nursing services is a qualified registered nurse employed full-time.				
F642	2. The director of nursing services has, in writing, administrative authority, responsibility, and accountability for the functions, activities, and training of the nursing services staff, and serves only one facility in this capacity.				
F643	3. If the director of nursing services has other institutional responsibilities, a qualified registered nurse serves as assistant so that there is the equivalent of a full-time director of nursing services on duty.				

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NAME OF FACILITY

CODE	NURSING SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
F644	B. **Health Services Supervision** ICF (442.339) (Standard) ☐ MET ☐ NOT MET				
F645	1. The facility has a full-time registered nurse, or a licensed practical or vocational nurse to supervise the health services 7 days a week on the day shift.				
F646	2. The nurse has a current State license.				
F647	3. If the supervisor of health services is a licensed practical or vocational nurse, the facility has a formal contract with a registered nurse to serve as a consultant no less than 4 hours a week.				
F648	4. To qualify to serve as a health services supervisor, a licensed practical or vocational nurse must: a. Have graduated from a State-approved school of practical nursing, or				
F649	b. Have education or other training that the State authority responsible for licensing practical nurses considered equal to graduation from a State-approved school of practical nursing, or				
F650	c. Have passed the Public Health Service examination for waivered licensed practical or vocational nurses.				
F651	5. If the nurse in charge is licensed by the State in a category other than registered nurse or licensed practical or vocational nurse: a. The individual has completed a training program to get the license that includes at least the same number of classroom and practice hours in all nursing subjects as in the program of a State-approved school of practical or vocational nursing, and				

NAME OF FACILITY

CODE	NURSING SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
F652	b. The State agency responsible for licensing the individual submits a report to the Medicaid agency comparing State-licensed practical nurse or vocational nurse course requirements with those for the program completed by the individual.				
	C. **Twenty-four Hour Nursing Service**				
F653	SNF (405.1124(c)) (Standard) ☐ MET ☐ NOT MET				
F654	ICF (442.338) (Standard) ☐ MET ☐ NOT MET				
F655	1. 24-Hour Nursing Nursing policies and procedures address the total nursing needs of the residents.				
F656	The policies are designed to ensure that each resident receives: Treatment.				
F657	Medications as prescribed.				
F658	Diet as prescribed.				
F659	Rehabilitative nursing care as needed.				
F660	Proper care to prevent decubitus ulcers and deformities.				
F661	Proper care to ensure that residents are clean, well-groomed and comfortable.				
F662	Protection from accident and injury.				
F663	Protection from infection.				
F664	Encouragement, assistance, and training in self-care and group activities.				

NAME OF FACILITY

CODE	NURSING SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
F665	2. Weekly time schedules are maintained and indicate the number and classifications of nursing personnel including relief personnel, who worked on each unit for each tour of duty			▨	
F666	D. **Rehabilitative Nursing Care** SNF (405.1124(e)) (Standard) ☐ MET ☐ NOT MET	▨	▨	▨	
F667	Nursing personnel are trained in rehabilitative nursing.			▨	
F658	E. **Supervision of Resident Nutrition** SNF (405.1124(f)) (Standard) ☐ MET ☐ NOT MET	▨	▨	▨	
F669	A procedure is established to inform dietetic service of physicians' diet orders and of residents' dietetic problems.			▨	
F670	F. **Administration of Drugs** SNF (405.1124(g)) (Standard) ☐ MET ☐ NOT MET	▨	▨	▨	
F671	Procedures are established by the Pharmaceutical Services Committee (see 405.1127(d)) to ensure that drugs are checked against physicians' orders.			▨	
F672	G. **Conformance with Physicians' Drug Orders** SNF (405.1124(h)) (Standard) ☐ MET ☐ NOT MET **Indicators 1 thru 4 apply to SNFs.**	▨	▨	▨	
F673	ICF (442.335) (Standard) ☐ MET ☐ NOT MET	▨	▨	▨	
F674	1. **Drugs not specifically limited as to time or number of doses when ordered are controlled by automatic stop orders or other methods in accordance with written policies.**			▨	

NAME OF FACILITY

CODE	NURSING SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
F675	2. The attending physician is notified of an automatic stop order prior to the last dose so that the physician may decide if the administration of the drug or biological is to be continued or altered.				
F676	ICF (442.334) (Standard) ☐ MET ☐ NOT MET				
F677	3. Physicians' verbal orders for drugs are given only to a licensed nurse, pharmacist, or physician and are immediately recorded and signed by the person receiving the order. (Verbal orders for Schedule II drugs are permitted only in the case of a bona fide emergency situation.)				
F678	4. Such orders are countersigned by the attending physician within a reasonable time.				
	H. **Storage of Drugs and Biologicals**				
F679	SNF (405.1124(i)) (Standard) ☐ MET ☐ NOT MET				
F680	1. Procedures for storing and disposing of drugs and biologicals are established by the pharmaceutical services committee.				
F681	2. In accordance with State and Federal laws, all drugs and biologicals are stored in locked compartments under proper temperature controls.				
F682	3. Only authorized personnel have access to the keys.				
F683	4. Separately locked, permanently affixed compartments are provided for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention & Control Act of 1970 and other drugs subject to abuse, except under single unit dosage distribution systems in which the quantity stored is minimal and a missing dose can be readily detected.				
F684	5. An emergency medication kit approved by the pharmaceutical services committee is kept readily available.				

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NAME OF FACILITY

CODE	DIETETIC SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	Dietetic Services *(Condition of Participation)*				
F685	SNF (405.1125) ☐ MET ☐ NOT MET The facility provides a hygienic dietetic service that meets the daily nutritional needs of patients, ensures that special dietary needs are met, and provides palatable and attractive meals. A facility that has a contract with an outside food management company may be found to be in compliance with this condition provided the facility and/or company meets the standards listed herein.				
	A. Staffing				
F686	SNF (405.1125(a)) (Standard) ☐ MET ☐ NOT MET				
F687	**1. Overall supervisory responsibility for the dietetic service is assigned to a full-time qualified dietetic service supervisor.**				
F688	**2. If the dietetic service supervisor is not a qualified dietitian, the dietetic service supervisor functions with frequent, regularly scheduled consultation from a person so qualified. (§405.1101(e).)**				
F689	**3. In addition, the facility employs sufficient supportive personnel competent to carry out the functions of the dietetic service.**				
F690	**4. If consultant dietetic services are used, the consultant's visits are at appropriate times, and of sufficient duration and frequency to provide continuing liaison with medical and nursing staffs, advice to the administrator, resident counseling, guidance to the supervisor and staff of the dietetic service, approval of all menus, and participation in the development or revisions of dietetic policies and procedures. (See §405.1121(i).)**				

NAME OF FACILITY

CODE	DIETETIC SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
F691	B. **Staffing** ICF (442.332) (Standard) ☐ MET ☐ NOT MET				
F692	1. The facility has a staff member trained or experienced in food management or nutrition who is responsible for: a. Planning meals that meet the nutritional needs of each resident.				
F693	b. Following the orders of the resident's physician.				
F694	c. To the extent medically possible, following the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences (Recommended Dietary Allowances, 8th Ed., 1974).				
F695	d. Supervising the meal preparation and service to ensure that the menu plan is followed.				
F696	2. For residents who required medically prescribed special diets, the facility: a. Has menus for those residents planned by a professionally qualified dietitian or reviewed and approved by the attending physician; and				
F697	b. Supervises the preparation and serving of meals to ensure that the resident accepts the special diet.				
F698	3. The facility keeps for 30 days a record of each menu as served.				

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NAME OF FACILITY

CODE	DIETETIC SERVICES/ SPECIALIZED REHABILITATION SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	C. **Hygiene of Staff**				
F699	SNF (405.1125(f)) (Standard) ☐ MET ☐ NOT MET				
F700	In the event food service employees are assigned duties outside the dietetic service, these duties do not interfere with the sanitation, safety, or the time required for dietetic work assignments. (See §405.1121(g).)				
	D. **Sanitary Conditions**				
F701	SNF (405.1125(g)) (Standard) ☐ MET ☐ NOT MET				
F702	Written reports of inspections by State and local health authorities are on file at the facility, with notation made of action taken by the facility to comply with any recommendations.				
	Specialized Rehabilitation Services *(Condition of Participation)*				
F703	SNF (405.1126) ☐ MET ☐ NOT MET The facility provides, or arranges for, under written agreement, specialized rehabilitative services by qualified personnel (i.e., physical therapy, speech pathology and audiology, and occupational therapy) as needed by residents to improve and maintain functioning. Safe and adequate space and equipment are available, commensurate with the services offered. If the facility does not offer such services directly, it does not admit nor retain residents in need of this care unless provision is made for such services under arrangement with qualified outside resources under which the facility assumes professional responsibility for the services rendered. (See §405.1121(i).)				

NAME OF FACILITY

CODE	SPECIALIZED REHABILITATION SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	A. **Staffing and Organization**				
F704	SNF (405.1126(a)) (Standard) ☐ MET ☐ NOT MET **Indicators 1 thru 3 apply to SNFs**				
F705	ICF (442.343) (Standard) ☐ MET ☐ NOT MET				
F706	1. **Specialized rehabilitative services are provided, in accordance with accepted professional practices, by qualified therapists or by qualified assistants or other supportive personnel under the supervision of qualified therapists.**				
F707	2. Other rehabilitative services also may be provided, but must be in a facility where all rehabilitative services are provided through an organized rehabilitative service under the supervision of a physician qualified in physical medicine who determines the goals and limitations of these services and assigns duties appropriate to the training and experience of those providing such services. **Exception: Does not apply to ICFs.**				
F708	3. Written administrative and resident care policies and procedures are developed for rehabilitative services by appropriate therapists and representatives of the medical, administrative, and nursing staffs. **Exception: Does not apply to ICF's** **See General Requirements 442.305**				

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CODE	SPECIALIZED REHABILITATION SERVICES/ PHARMACEUTICAL SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
F709	**B. Documentation of Services** SNF (405.1126(c)) (Standard) ☐ MET ☐ NOT MET The physician's order, the plan of rehabilitative care, services rendered, evaluations of progress, and other pertinent information are recorded in the patient's medical record, and are dated and signed by the physician ordering the service and the person who provided the service.				
F710	C. **Qualifying to Provide Outpatient Physical Therapy Services** SNF (405.1126(d)) (Standard) ☐ MET ☐ NOT MET If the facility provides outpatient physical therapy services, it meets the applicable health and safety regulations pertaining to such services as are included in Subpart Q of this part. (See §405.1719, 405.1720, 405.1722(a) and (b)(1)(2)(3)(i), (4), (5), (6), (7), and (8); and 405.1725.)				
F711	**Pharmaceutical Services *(Condition of Participation)*** SNF (405.1127) ☐ MET ☐ NOT MET The facility has appropriate methods and procedures for the dispensing and administering of drugs and biologicals. The facility is responsible for providing such drugs and biologicals for its residents, insofar as they are covered under the programs, and for ensuring that pharmaceutical services are provided in accordance with accepted professional principles.				

NAME OF FACILITY

CODE	PHARMACEUTICAL SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
F712	**A. Supervision of Services** SNF (405.1127(a)) (Standard) ☐ MET ☐ NOT MET	▨	▨	▨	
F713	1. The pharmaceutical services are under the general supervision of a qualified pharmacist.			▨	
F714	2. The pharmacist is responsible to the administrative staff for developing coordinating, and supervising all pharmaceutical services.			▨	
F715	3. The pharmacist (if not a full-time employee) devotes a sufficient number of hours, based upon the needs of the facility, during regularly scheduled visits to carry out these responsibilities.			▨	
F716	ICF (442.333) (Standard) ☐ MET ☐ NOT MET	▨	▨	▨	
F717	1. The facility employs a licensed pharmacist, or				
F718	2. The facility has formal arrangements with a licensed pharmacist to advise the facility on ordering, storage, administration, disposal and recordkeeping of drugs and biologicals.				
F719	**B. Control and Accountability** SNF (405.1127(b)) (Standard) ☐ MET ☐ NOT MET	▨	▨	▨	
F720	1. The pharmaceutical service has procedures for control and accountability of all drugs and biologicals throughout the facility.			▨	
F721	2. Only approved drugs and biologicals are used in the facility.			▨	
F722	3. Records of receipt and disposition of all controlled drugs are maintained in sufficient detail to enable an accurate reconciliation.			▨	

NAME OF FACILITY

CODE	PHARMACEUTICAL SERVICES/ LABORATORY AND RADIOLOGIC SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
F723	C. **Pharmaceutical Services Committee** SNF (405.1127(d)) (Standard) ☐ MET ☐ NOT MET				
F724	1. A pharmaceutical services committee or its equivalent develops written policies and procedures for safe and effective drug therapy, distribution, control and use.				
F725	2. The committee is comprised of at least the pharmacist, the director of nursing services, the administrator, and one physician.				
F726	3. The committee oversees pharmaceutical services in the facility, makes recommendations for improvement, and monitors the service to ensure its accuracy and adequacy.				
F727	**Laboratory and Radiologic Services** ***(Condition of Participation)*** SNF (405.1128) ☐ MET ☐ NOT MET The facility has provision for promptly obtaining required laboratory, X-ray, and other diagnostic services.				
F728	A. **Provision for Services** SNF (405.1128(a)) (Standard) ☐ MET ☐ NOT MET				
F729	1. If the facility provides its own laboratory and X-ray services, these meet the applicable conditions established for certification of hospitals that are contained in 405.1028 and 405.1029, respectively.				

NAME OF FACILITY

CODE	LABORATORY AND RADIOLOGIC SERVICES/ DENTAL SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
F730	2. If the facility itself does not provide such services, arrangements are made for obtaining these services from a physician's office, a participating hospital or skilled nursing facility, or a portable X-ray supplier or independent laboratory which is approved to provide these services under the program.				
F731	3. The facility assists the resident, if necessary, in arranging for transportation to and from the source of service.				
F732	B. **Blood and Blood Products** SNF (405.1128(b)) (Standard) ☐ MET ☐ NOT MET	▨	▨	▨	
F733	1. Blood handling and storage facilities are safe, adequate, and properly supervised.				
F734	2. If the facility provides for maintaining and transfusing blood and blood products, it meets the conditions established for certification of hospitals that are contained in §405.1028(j).				
F735	3. If the facility does not provide its own facility but does provide transfusion services alone, it meets at least the requirements of §405.1028(j)(1), (3), (4), (6), and (9).				
F736	**Dental Services** ***(Condition of Participation)*** SNF (405.1129) ☐ MET ☐ NOT MET The facility has satisfactory arrangements to assist residents to obtain routine and emergency dental care (See §405.1121(i). (The basic Hospital Insurance Program does not cover the services of a dentist in a skilled nursing facility in connection with the care, treatment, filling, removal, or replacement of teeth or structures supporting the teeth; and only certain oral surgery is included in the Supplemental Medical Insurance Program.)	▨	▨	▨	

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NAME OF FACILITY

CODE	DENTAL SERVICES/SOCIAL SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
F737	A. **Advisory Dentist** SNF (405.1129(a)) (Standard) ☐ MET ☐ NOT MET				
F738	A dentist recommends oral hygiene policies and practices for the care of residents. (§405.1121(h).				
F739	B. **Arrangements of Outside Services** SNF (405.1129(b)) (Standard) ☐ MET ☐ NOT MET				
F740	1. The facility has a cooperative agreement with a dentist, and				
F741	2. Maintains a list of dentists in the community for residents who do not have a private dentist.				
F742	3. The facility assists the resident, if necessary, in arranging for transportation to and from the dentist's office.				
F743	**Social Services *(Condition of Participation)*** SNF (405.1130) ☐ MET ☐ NOT MET The facility has satisfactory arrangements for identifying the medically related social and emotional needs of the resident. It is not mandatory that the skilled nursing facility itself provide social services in order to participate in the program. If the facility does not provide social services, it has written procedures for referring residents in need of social services to appropriate social agencies. If social services are offered by the facility, they are provided under a clearly defined plan, by qualified persons, to assist each resident to adjust to the social and emotional aspects of the resident's illness, treatment, and stay in the facility.				

NAME OF FACILITY

CODE	SOCIAL SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	A. **Social Service Functions**				
F744	SNF (405.1130(a)) (Standard) ☐ MET ☐ NOT MET				
F745	Services are provided to meet the social and emotional needs of residents by qualified staff of the facility, or by referral, based on established procedures, to appropriate social agencies.				
F746	ICF (442.344(b)) ☐ MET ☐ NOT MET The facility either provides these services itself or arranges for them with qualified outside resources.				
	B. **Staffing**				
F747	SNF (405.1130(b)) (Standard) ☐ MET ☐ NOT MET				
F748	1. If the facility offers social services, a member of the staff of the facility is designated as responsible for social services.				
F749	2. If the designated person is not a qualified social worker, the facility has a written agreement with a qualified social worker or recognized social agency for consultation and assistance on a regularly scheduled basis. (See §405.1101(s).)				
F750	3. The social service also has sufficient supportive personnel to meet resident needs.				
F751	4. Facilities are adequate for social service personnel, easily accessible to residents and medical and other staff, and ensure privacy for interviews.				

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NAME OF FACILITY

CODE	SOCIAL SERVICES/ACTIVITIES	YES	NO	N/A	EXPLANATORY STATEMENT
F752	ICF (442.344(c)) ☐ MET ☐ NOT MET				
F753	The facility designates one staff member, qualified by training or experience, to be responsible for: a. Arranging for social services; and				
F754	b. Integrating social services with other elements of the plan of care.				
	C. **Records and Confidentiality**				
F755	SNF (405.1130(c)) (Standard) ☐ MET ☐ NOT MET				
F756	Records of pertinent social data about personal and family problems medically related to the resident's illness and care, and of action taken to meet the resident's needs, are maintained in the resident's medical records.				
F757	If social services are provided by an outside resource, a record is maintained of each referral to such resource.				
	Activities (Condition of Participation)				
F758	SNF (405.1131) ☐ MET ☐ NOT MET The facility provides for an activities program, appropriate to the needs and interests of each resident, to encourage self care, resumption of normal activities, and maintenance of an optimal level of psychosocial functioning.				

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NAME OF FACILITY

CODE	ACTIVITIES/MEDICAL RECORDS	YES	NO	N/A	EXPLANATORY STATEMENT
	A. Staffing				
F759	SNF (405.1131(a)) (Standard) ☐ MET ☐ NOT MET				
F760	A member of the facility's staff is designated as responsible for the activities program.				
F761	If not a qualified activities coordinator, this staff member functions with frequent, regularly scheduled consultation from a person so qualified. (See §405.1101(o).)				
F762	ICF (442.345(b)) ☐ MET ☐ NOT MET The facility designates one staff member, qualified by training or experience in directing group activity, to be responsible for activity service.				
	Medical Records *(Condition of Participation)*				
F763	SNF (405.1132) ☐ MET ☐ NOT MET The facility maintains clinical (medical) records on all residents in accordance with accepted professional standards and practices. The medical record service has sufficient staff, facilities, and equipment to provide medical records that are completely and accurately documented, readily accessible, and systematically organized to facilitate retrieving and compiling information.				
F764	ICF (442.318(a)) ☐ MET ☐ NOT MET The facility maintains an organized resident record system that contains a record for each resident.				

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NAME OF FACILITY

CODE	MEDICAL RECORDS	YES	NO	N/A	EXPLANATORY STATEMENT
	A. Staffing	▨	▨	▨	
F765	SNF (405.1132(a)) (Standard) ☐ MET ☐ NOT MET	▨	▨	▨	
F766	1. Overall supervisory responsibility for the medical record service is assigned to a full-time employee of the facility.			▨	
F767	2. The facility also employs sufficient supportive personnel competent to carry out the functions of the medical record service.			▨	
F768	3. If the medical record supervisor is not a qualified medical record practitioner, this person functions with consultation from a person qualified. (See §405.1101(l).)				
	B. Protection of Medical Record Information	▨	▨	▨	
F769	SNF (405.1132(b)) (Standard) ☐ MET ☐ NOT MET	▨	▨	▨	
F770	ICF (442.318(d)) ☐ MET ☐ NOT MET	▨	▨	▨	
F771	The facility safeguards medical record information against loss, destruction, or unauthorized use.			▨	
	C. Physician Documentation	▨	▨	▨	
F772	SNF (405.1132(d)) (Standard) ☐ MET ☐ NOT MET	▨	▨	▨	
F773	1. Only physicians enter or authenticate in medical records opinions that require medical judgment (in accordance with medical staff bylaws, rules, and regulations, if applicable).			▨	
F774	2. All physicians sign their entries into the medical record.			▨	

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NAME OF FACILITY

CODE	MEDICAL RECORDS	YES	NO	N/A	EXPLANATORY STATEMENT
F775	**D. Completion of Records and Centralization of Reports** SNF (405.1132(e)) (Standard) ☐ MET ☐ NOT MET	▨	▨	▨	
F776	1. Current medical records and those of discharged residents are completed promptly.			▨	
F777	2. All clinical information pertaining to a resident's stay is centralized in the resident's medical record.			▨	
F778	**E. Retention and Preservation** SNF (405.1132(f)) (Standard) ☐ MET ☐ NOT MET Medical records are retained for a period of time not less than that determined by the respective State statute, the statue of limitations in the State, or 5 years from the date of discharge in the absence of a State statute, or, in the case of a minor, 3 years after the resident becomes of age under State law.	▨	▨	▨	
F779	ICF (442.318(e)) ☐ MET ☐ NOT MET The facility must keep a resident's record for at least 3 years after the resident is discharged.	▨	▨	▨	
F780	**F. Location and Facilities** SNF (405.1132(h)) (Standard) ☐ MET ☐ NOT MET The facility maintains adequate facilities and equipment, conveniently located to provide efficient processing of medical records (reviewing, indexing, filing, and prompt retrieval).	▨	▨	▨	

NAME OF FACILITY

CODE	TRANSFER AGREEMENT	YES	NO	N/A	EXPLANATORY STATEMENT
	Transfer Agreement ***(Condition of Participation)***				
F781	SNF (405.1133) ☐ MET ☐ NOT MET				
F782	ICF (442.316) (Standard) ☐ MET ☐ NOT MET				
F783	The facility has in effect a transfer agreement with one or more hospitals approved for participation under the programs, which provides the basis for effective working arrangements under which inpatient hospital care or other hospital services are available promptly to the facility's residents when needed. (A facility that has been unable to establish a transfer agreement with the hospital(s) in the community or service area after documented attempts to do so is considered to have such an agreement in effect.) Exception: A facility that has been unable to establish a written agreement after documented attempts to do so, is considered to have such an agreement.				
	Resident Transfer				
F784	SNF (405.1133(a)) (Standard) ☐ MET ☐ NOT MET				
F735	**A hospital and a skilled nursing facility shall be considered to have a transfer agreement in effect if, by reason of a written agreement between them or (in case of two institutions are under common control) by reason of a written undertaking by the person or body which controls them, there is reasonable assurance that:** **1. Transfer of patients will be effected between the hospital and the skilled nursing facility, ensuring timely admission, whenever such transfer is medically appropriate as determined by the attending physician.**				

NAME OF FACILITY

CODE	TRANSFER AGREEMENT/PHYSICAL ENVIRONMENT	YES	NO	N/A	EXPLANATORY STATEMENT
F786	2. There will be interchange of medical and other information necessary or useful in the care and treatment of individuals transferred between institutions, or in determining whether such individuals can be adequately cared for otherwise than in either of such institutions.				
F787	3. Security and accountability for residents' personal effects are provided on transfer.				
	Physical Environment *(Condition of Participation)*				
F788	SNF (405.1134) ☐ MET ☐ NOT MET The facility is constructed, equipped, and maintained to protect the health and safety or residents, personnel, and the public.				
	A. **Life Safety from Fire** SNF (405.1134(a)) (Standard) ☐ MET ☐ NOT MET				
	ICF (442.321) (Standard) ☐ MET ☐ NOT MET				
	(See appropriate HCFA Fire Safety survey form.)				
	B. **Maintenance of Equipment, Building, and Grounds**				
F789	SNF (405.1134(i)) (Standard) ☐ MET ☐ NOT MET				
F790	The facility establishes a written preventative maintenance program to ensure that all equipment is operative.				

NAME OF FACILITY

CODE	INFECTION CONTROL	YES	NO	N/A	EXPLANATORY STATEMENT
	Infection Control ***(Condition of Participation)***				
F791	SNF (405.1135) ☐ MET ☐ NOT MET The facility establishes an infection control committee of representative professional staff with responsibility for overall infection control in the facility. All necessary housekeeping and maintenance services are provided to maintain a sanitary and comfortable environment and to help prevent the development and transmission of infection.				
	A. **Infection Control Committee**				
F792	SNF (405.1135(a)) (Standard) ☐ MET ☐ NOT MET				
F793	1. The infection control committee is composed of members of the medical and nursing staffs, administration, and the dietetic, pharmacy, housekeeping, maintenance, and other services.				
F794	2. The committee establishes policies and procedures for investigating, controlling, and preventing infection in the facility.				
F795	3. The committee monitors staff performance to ensure that the policies and procedures are executed.				
	B. **Aseptic and Isolation Techniques**				
F796	SNF (405.1135(b)) (Standard) ☐ MET ☐ NOT MET				
F797	1. The facility has written procedures for aseptic and isolation techniques.				
F798	2. These procedures are reviewed and revised for effectiveness and improvement as necessary.				

NAME OF FACILITY

CODE	INFECTION CONTROL	YES	NO	N/A	EXPLANATORY STATEMENT
F799	C. **Housekeeping** SNF (405.1135(c)) (Standard) ☐ MET ☐ NOT MET	▨	▨	▨	
F800	1. The facility employs sufficient housekeeping personnel.			▨	
F801	2. Provides all necessary equipment to maintain a safe, clean and orderly interior.			▨	
F802	3. A full-time employee is designated responsible for the services and for supervision and training of personnel.			▨	
F803	4. If a facility has a contract with an outside resource for housekeeping services, the facility and/or outside resource meets the requirements of the standards.				
F804	D. **Pest Control** SNF (405.1135(e)) (Standard) ☐ MET ☐ NOT MET The facility has an ongoing pest control program.	▨	▨	▨	

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NAME OF FACILITY

CODE	DISASTER PREPAREDNESS	YES	NO	N/A	EXPLANATORY STATEMENT
	Disaster Preparedness *(Condition of Participation)*				
F805	SNF (405.1136) ☐ MET ☐ NOT MET The facility has a written plan, periodically rehearsed, with procedures to be followed in the event of an internal or external disaster and for the care of casualties (residents and personnel) arising from such disasters.				
	A. Plan				
F806	ICF (442.313) (Standard) ☐ MET ☐ NOT MET				
F807	1. The facility has a written plan for staff and residents to follow in case of emergencies such as fire or explosion.				
F808	2. The facility rehearses the plan regularly.				
F809	3. The facility has written procedures for the staff to follow in case of an emergency involving an individual resident.				
F810	4. These procedures include: a. Caring for the resident.				
F811	b. Notifying the attending physician and other individuals responsible for the resident.				
F812	c. Arranging for transportation, hospitalization, and other appropriate services.				
F813	SNF (405.1136(a)) (Standard) ☐ MET ☐ NOT MET				
F814	1. The facility has an acceptable written plan in operation, with procedures to be followed in the event of fire, explosion, or other disaster.				
F815	2. The plan is developed and maintained with the assistance of qualified fire, safety, and other appropriate experts.				

NAME OF FACILITY

CODE	DISASTER PREPAREDNESS/UTILIZATION REVIEW	YES	NO	N/A	EXPLANATORY STATEMENT
F816	3. Includes procedures for prompt transfer of casualties and records.			▨	
F817	4. Instructions regarding the location and use of alarm systems and signals and of fire-fighting equipment.			▨	
F818	5. Information regarding methods of containing fire.			▨	
F819	6. Procedures for notification of appropriate persons.			▨	
F820	7. Specifications of evacuation routes and procedures. (See §405.1134(a).)			▨	
	B. Orientation and training	▨	▨	▨	
F821	SNF (405.1136(b)) (Standard) ☐ MET ☐ NOT MET	▨	▨	▨	
F822	The disaster program includes orientation and ongoing training and drills for all personnel in all procedures so that each employee promptly and correctly carries out a specific role in case of a disaster (See §405.1121(h).)			▨	
	Utilization Review ***(Condition of Participation)***	▨	▨	▨	
F823	SNF (405.1137) ☐ MET ☐ NOT MET The facility carries out utilization review of the services provided in the facility to residents who are entitled to benefits under the program(s). Utilization review assures the maintenance of high quality care and appropriate and efficient utilization of facility services. There are two elements to utilization review: medical care evaluation studies and review of extended duration cases.	▨	▨	▨	

NAME OF FACILITY

CODE	UTILIZATION REVIEW	YES	NO	N/A	EXPLANATORY STATEMENT
F824	A. **Plan** SNF (405.1137(a)) (Standard) ☐ MET ☐ NOT MET	▨	▨	▨	
F825	1. The facility has a currently applicable written description of its utilization review plan.			▨	
F826	2. Such description includes: a. The organization and composition of the committee or group which will be responsible for the utilization review function.			▨	
F827	b. Methods of criteria (including norms where available) to be used to define periods of continuous extended duration and to assign or select subsequent dates for continued stay review.			▨	
F828	c. Methods for selection and conduct of medical care evaluation studies.			▨	
F829	B. **Organization and Composition of Utilization Review Committees** SNF (405.1137(b)) (Standard) ☐ MET ☐ NOT MET	▨	▨	▨	
F830	1. The utilization review (UR) function is conducted by: a. A staff committee of the skilled nursing facility which is composed of two or more physicians, with participation of other professional personnel; or,				

NAME OF FACILITY

CODE	UTILIZATION REVIEW	YES	NO	N/A	EXPLANATORY STATEMENT
F831	b. A group outside the facility which is similarly composed and which is established by the local medical or osteopathic society and some or all of the hospitals and skilled nursing facilities in the locality; or (indicate name of the outside group and briefly describe the organization.)				
F832	c. A group established and organized in a manner approved by the Secretary that is capable of performing such function.				
F833	2. The medical care evaluation studies, educational duties of the review program, and the review of admissions and long-stay cases are performed by: a. the same committee or group;				
F834	b. or more committees or groups. Briefly explain who performs these functions.				
F835	C. **Medical Care Evaluation Studies** SNF (405.1137(c)) (Standard) ☐ MET ☐ NOT MET				
F836	1. Medical care evaluation studies are performed to promote the most effective and efficient use of available health facilities and services consistent with resident needs and professionally recognized standards of health care.				
F837	2. Studies emphasize identification and analysis of patterns of resident care and suggest, where appropriate, possible changes for maintaining consistently high quality care and effective and efficient use of services.				

NAME OF FACILITY

CODE	UTILIZATION REVIEW	YES	NO	N/A	EXPLANATORY STATEMENT
F838	3. Each medical care evaluation study identifies and analyzes factors related to the care rendered in the facility and where indicated, results in recommendations for change beneficial to residents, staff, the facility, and the community.			▨	
F839	4. Studies, on a sample or other basis, include, but need not be limited to, admissions, durations of stay, ancillary services furnished (including drugs and biologicals), and professional services performed on premises.			▨	
F840	At least one study was completed during the last year. Type of study last completed: ______________			▨	
	D. **Extended Stay Review**				
F841	SNF (405.1137(d)) (Standard) ☐ MET ☐ NOT MET	▨	▨	▨	
F842	1. Periodic review is made of each current inpatient skilled nursing facility beneficiary case of continuous extended duration, and the length of which is defined in the utilization review plan to determine whether further inpatient stay is necessary.			▨	
F843	2. The review is based on the attending physician's reasons for and plan for continued stay and any other documentation the committee or group deems appropriate.			▨	
F844	3. Cases are screened by: a. A qualified non-physician representative of the committee.				
F845	b. The group.				
F846	c. The reviewer uses criteria established by the physician members of the committee.				

NAME OF FACILITY

CODE	UTILIZATION REVIEW	YES	NO	N/A	EXPLANATORY STATEMENT
F847	4. In instances when non-physician members are utilized, those cases are referred to a physician member for further review when it appears that the resident no longer requires further inpatient care.				
F848	5. Non-physician representatives used to screen extended stay review cases, have experience in such screening or appropriate training in the application of the screening criteria used, or both.				
F849	6. Before the expiration of each new period, the case must be reviewed again in like manner with such reviews being repeated as long as the stay continues beyond the scheduled review dates and notice has not been given pursuant to paragraph (e) of this section.				
F850	E. **Further Stay Not Medically Necessary** SNF (405.1137(e)) (Standard) ☐ MET ☐ NOT MET				
F851	1. A final determination of the committee or group that continued stay is not medically necessary is made by at least two physician members of the committee or group, except that the final determination may be made by one physician where the attending physician, when given an opportunity to express his views, does not do so, or does not contest the finding that the continued stay is not medically necessary.				
F852	2. If the committee or group, or its nonphysician representative where a physician member concurs, has reason to believe from the review of an extended duration case or a case reviewed as part of a medical care evaluation study that further stay is no longer medically necessary, the committee or group shall notify the individual's attending physician and afford him an opportunity to present his views before it makes a final determination.				

NAME OF FACILITY

CODE	UTILIZATION REVIEW	YES	NO	N/A	EXPLANATORY STATEMENT
F853	3. If the final determination of the committee or group is that further stay is no longer medically necessary, written notification of the finding is given to the facility, the attending physician, and the individual (or where appropriate, his next of kin) no later than 2 days after such final determination is made and, in no event in the case of an extended duration case, later than 3 working days after the end of the extended duration period specified pursuant to paragraph (d) of this section.				
	F. **Administrative Responsibilities**				
F854	SNF (405.1137(f)) (Standard) ☐ MET ☐ NOT MET				
F855	The administrative staff of the facility is kept directly and fully informed of committee activities to facilitate support and assistance. (Explain)				
	G. **Utilization Review Records**				
F856	SNF (405.1137(g)) (Standard) ☐ MET ☐ NOT MET				
F857	1. Written records of committee activities are maintained.				
F858	2. Appropriate reports, signed by the committee chairman, are made regularly to the medical staff, administrative staff, governing body, and sponsors (if any).				
F859	3. Minutes of each committee meeting is maintained and include at least: a. Name of committee.				
F860	b. Date and duration of meeting.				
F861	c. Names of committee members present and absent.				

NAME OF FACILITY

CODE	UTILIZATION REVIEW	YES	NO	N/A	EXPLANATORY STATEMENT
F862	4. Description of activities presently in progress to satisfy the requirements for medical care evaluation studies, including the subject, reason for study, dates of commencement and expected completion, summary of studies completed since the last meeting, conclusions and follow-up on implementation of recommendations made from previous studies.				
F863	5. Summary of extended duration cases reviewed including the number of cases, identification number, admission and review dates, and decision reached, including the basis for each determination and action taken for each case not approved for extended care.				
	H. **Discharge Planning**				
F864	SNF (405.1137(h)) (Standard) ☐ MET ☐ NOT MET The facility maintains a centralized, coordinated program to ensure that each resident has a planned program of continuing care which meets his postdischarge needs.				
F865	1. The facility has in operation an organized discharge planning program.				
F866	The utilization review committee, in its evaluation of the current status of each extended duration case, has available to it the results of such discharge planning and information on alternative available community resources to which the resident may be referred.				
F867	2. The facility maintains written discharge planning procedures which describe: a. How the discharge coordinator will function, and his authority and relationships with the facility's staff.				
F868	b. The maximum time period after which reevaluation of each resident's discharge plan is made.				

NAME OF FACILITY

CODE	UTILIZATION REVIEW	YES	NO	N/A	EXPLANATORY STATEMENT
F869	c. Local resources available to the facility, the resident, and the attending physician to assist in developing and implementing individual discharge plans; and			▨	
F870	d. Provisions for periodic review and reevaluation of the facility's discharge planning program.			▨	
F871	3. At the time of discharge, the facility provides those responsible for the resident's post discharge care with appropriate summary of information about the discharged resident to ensure the optimal continuity of care.			▨	
	The discharge summary includes at least the following:			▨	
F872	a. Current information relative to diagnoses.				
F873	b. Rehabilitation potential.			▨	
F874	c. A summary of the course of prior treatment.			▨	
F875	d. Physician orders for the immediate care of the resident.			▨	
F876	e. Pertinent social information.			▨	

§ 488.105 Long term care survey forms, Part B.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO. 0938-0400

PART B

MEDICARE / MEDICAID SKILLED NURSING FACILITY AND INTERMEDIATE CARE FACILITY SURVEY REPORT

LONG TERM CARE SURVEY

PROVIDER NUMBER

VENDOR NUMBER

SURVEY DATE

FACILITY NAME AND ADDRESS (City, State, Zi[illegible]

SURVEYORS' NAMES	TITLES

SURVEY TEAM COMPOSITION

F1 Indicate the Number of Surveyors According to Discipline

- A. ☐ Administrator
- B. ☐ Nurse
- C. ☐ Dietitian
- D. ☐ Pharmacist
- E. ☐ Records Administrator
- F. ☐ Social Worker
- G. ☐ Qualified Mental Retardation Professional
- H. ☐ Life Safety Code Specialist
- I. ☐ Laboratorian
- J. ☐ Sanitarian
- K. ☐ Therapist
- L. ☐ Physician
- M. ☐ National Institute of Mental Health
- N. ☐ Other

Note: More than one disc[illegible]ay be marked for surveyors qualified in multiple disciplines.

F2 Indicate the Total Number of Surveyors Onsite: ________________

Form HCFA-519 (2-86)

(CONTINUED ON REVERSE)

Page 1

RESIDENT CENSUS AND CONDITIONS OF RESIDENTS

PROVIDER NO. ________ F3 ☐ MEDICARE ________ F4 ☐ MEDICAID ________ F5 ☐ OTHER ______ F6 TOTAL RESIDENTS ______

CODE	
	BATHING
F7	___ Number of residents requiring assistance in bathing more than one part of body—or does not bathe self.
F8	___ Number of residents requiring assistance in bathing only a single part (as back or disabled extremity) or bathes self completely.
F9	___ TOTAL*
	DRESSING
F10	___ Number of residents totally dressed by another person.
F11	___ Number of residents needing assistance to dress self or remain partly dressed. (Exclude those residents totally dressed.)
F12	___ Number of residents able to get clothes from closets and drawers-puts on clothes, outer garments, braces-manages fasteners. Act of tying shoes is excluded.
F13	___ TOTAL*
	TOILETING
F14	___ Number of residents not toileted. (Use protective padding, catheter.)
F15	___ Number of residents who must use a bedpan or commode and/or receive assistance in getting to and using a toilet.
F16	___ Number of residents able to get to toilet—gets on and off toilet—cleans self—arranges clothes.
F17	___ TOTAL*
	TRANSFERRING
F18	___ Number of residents needing assistance in all transfers (moving in or out of bed and/or chair, toilet, tub transfers).
F19	___ Number of residents needing assistance in transferring to toilet and tub only.
F20	___ Number of residents able to complete all transfers independently (may or may not be using mechanical supports).
F21	___ Total*

CODE	
	CONTINENCE
F22	___ Number of residents with indwelling or external catheters.
F23	___ Number of residents with partial or total incontinence in urination or defecation—partial or total control by suppositories or enemas, regulated use of urinals and/or bedpans.
F24	___ Number of residents with urination and defecation entirely self-controlled.
F25	___ TOTAL*
	FEEDING
F26	___ Number of residents who receive enteral/parenteral feedings.
F27	___ Number of residents who receive NG tube feedings.
F28	___ Number of residents who require assistance in act of eating.
F29	___ Number of residents who get food from plate or its equivalent into mouth—(pre-cutting of meat and preparation of food, buttering bread, opening cartons, removing plate covers, etc., are *excluded* from evaluation).
F30	___ TOTAL*
F31	___ Number of completely bedfast residents.
F32	___ Number of chairbound residents.
F33	___ Number of ambulatory residents (may use cane, walker, or crutches).
F34	___ Number of physically restrained residents (belt, vest, cuffs).
F35	___ Number of residents receiving psychotropic drugs.
F36	___ Number of confused or disoriented residents.
F37	___ Number of residents with decubiti.
F38	___ Number of residents on individually written bowel and bladder retraining program.
F39	___ Number of residents receiving special skin care.
F40	___ Number of residents receiving intravenous therapy and/or blood transfusion.
F41	___ Number of residents requiring no assistance in ADLs.
F42	___ Number of residents on self-administration of drugs.
F43	___ Number of residents with contractures.
F44	___ Number of residents receiving respiratory care.
F45	___ Number of residents receiving tracheostomy care.
F46	___ Number of residents receiving suctioning.
F47	___ Number of residents receiving rehabilitative services (physical therapy, speech pathology and audiology, occupational therapy)
F48	___ Number of residents receiving injections.
F49	___ Number of residents receiving colostomy care.

Form HCFA-[illegible] *MUST EQUAL TOTAL NUMBER OF RESIDENTS IN FACILITY Page [illegible]

NAME OF FACILITY

CODE	GOVERNING BODY	YES	NO	N/A	EXPLANATORY STATEMENT
	GOVERNING BODY ***(CONDITION OF PARTICIPATION)***				
F50	SNF (405.1121) ☐ MET ☐ NOT MET				
	RESIDENT RIGHTS				
F51	SNF (405.1121(k)) (Standard) ☐ MET ☐ NOT MET Indicators A thru K apply to this standard for SNFs				
F52	ICF (442.311) (Standard) ☐ MET ☐ NOT MET Indicators A thru K apply to this standard for ICFs				
	A. Information				
F53	1. The facility informs each resident, before or at the time of admission, of his/her rights and responsibilities.				
F54	2. The facility informs each resident, before or at the time of admission, of all rules governing resident conduct.				
F55	3. The facility informs each resident of amendments to their policies on residents' rights and responsibilities and rules governing conduct.				
F56	4. Each resident acknowledges in writing receipt of residents' rights information and any amendment to it.				
F57	5. The resident must be informed in writing of all services and charges for services.				
F58	6. The resident must be informed in writing of all changes in services and charges before or at the time of admission and on a continuing basis.				
F59	7. The resident must be informed of services not covered by Medicare or Medicaid and not covered in the basic rate.				

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Page 3

NAME OF FACILITY

CODE	GOVERNING BODY	YES	NO	N/A	EXPLANATORY STATEMENT
	B. Medical Condition and Treatment				
F60	1. Each resident is informed by a physician of his/her health and medical condition unless the physician decides that informing the resident is medically contraindicated.				
F61	2. Each resident is given an opportunity to participate in planning his/her total care and medical treatment.				
F62	3. Each resident is given an opportunity to refuse treatment.				
F63	4. Each resident gives informed, written consent before participating in experimental research.				
F64	5. If the physician decides that informing the resident of his/her health and medical condition is medically contraindicated, the physician has documented this decision in the resident's medical record.				
	C. **Transfer and Discharge** Each resident is transferred or discharged only for:				
F65	1. Medical reasons.				
F66	2. His/her welfare or that of other residents.				
F67	3. Nonpayment except as prohibited by the Medicare or Medicaid program.				
F68	4. Each resident is given reasonable advance notice to ensure orderly transfer or discharge. EXCEPTION: Not required for ICF residents.				
	D. **Exercising Rights**				
F69	1. Each resident is encouraged and assisted to exercise his/her rights as a resident of the facility and as a citizen.				
F70	2. Each resident is allowed to submit complaints and recommendations concerning the policies and services of the facility to staff or to outside representatives of the resident's choice or both.				

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Page 4

NAME OF FACILITY

CODE	GOVERNING BODY	YES	NO	N/A	EXPLANATORY STATEMENT
F71	3. Such complaints are submitted free from restraint, coercion, discrimination, or reprisal.				
	E. Financial Affairs				
F72	**1. Residents are allowed to manage their own personal financial affairs.**				
F73	**2. The facility establishes and maintains a system that assures full and complete accounting of residents' personal funds. An accounting report is made to each resident in a skilled nursing facility at least on a quarterly basis.**				
F74	**3. The facility does not commingle resident funds with any other funds.**				
F75	**4. If a resident requests assistance from the facility in managing his/her personal financial affairs, resident's delegation is in writing.**				
	5. The facility system of accounting includes written receipts for:				
F76	**All personal possessions and funds received by or deposited with the facility.**				
F77	**All disbursements made to or for the resident.**				
F78	**6. The financial record must be available to the resident and his/her family.**				
	F. Freedom from Abuse and Restraints				
F79	**1. Each resident is free from mental and physical abuse.**				
F80	**2. Chemical and physical restraints are only used when authorized by a physician in writing for a specified period of time or in emergencies.**				

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Page 5

NAME OF FACILITY

CODE	GOVERNING BODY	YES	NO	N/A	EXPLANATORY STATEMENT
F81	3. If used in emergencies, they are necessary to protect the resident from injury to himself/herself or others.				
F82	4. The emergency use is authorized by a professional staff member identified in the written policies and procedures of the facility.				
F83	5. The emergency use is reported promptly to the resident's physician by the staff member.				
	G. Privacy				
F84	1. Each resident is treated with respect, consideration and full recognition of his/her dignity and individuality.				
F85	2. Each resident is given privacy during treatment and care of personal needs.				
F86	3. Each resident's records, including information in an automated data bank, are treated confidentially.				
F87	4. Each resident must give written consent before the facility releases information from his/her record to someone not otherwise authorized to receive it.				
F88	5. Married residents are given privacy during visits by their spouses.				
F89	6. Married residents are permitted to share a room.				
	H. Work				
F90	No resident may be required to perform services for the facility.				

NAME OF FACILITY

CODE	GOVERNING BODY	YES	NO	N/A	EXPLANATORY STATEMENT
F91	**I. Freedom of Association and Correspondence** **1. Each resident is allowed to communicate, associate and meet privately with individuals of his/her choice unless this infringes upon the rights of another resident.**			▨	
F92	**2. Each resident is allowed to send and receive personal mail unopened.**			▨	
F93	**J. Activities** **Each resident is allowed to participate in social, religious, and community group activities.**			▨	
F94	**K. Personal Possessions** **Each resident is allowed to retain and use his/her personal possessions and clothing as space permits.**			▨	
F95	**L. Delegation of Rights and Responsibilities** **ICF (442.312)** (Standard) ☐ **MET** ☐ **NOT MET**	▨	▨	▨	
F96	**1. All the rights and responsibilities of a resident pass to the resident's guardian, next of kin or sponsoring agency or agencies if the resident is adjudicated incompetent under State law or is determined by his/her physician to be incapable of understanding his/her rights and responsibilities.**			▨	
F97	**2. Physician determinations of incapability and the specific reasons thereof are recorded by the physician in the resident's record.**			▨	

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NAME OF FACILITY

CODE	GOVERNING BODY	YES	NO	N/A	EXPLANATORY STATEMENT
F98	STAFF DEVELOPMENT SNF (405.1121(h)) (Standard) ☐ MET ☐ NOT MET				
F99	ICF (442.314) (Standard) ☐ MET ☐ NOT MET				
F100	1. Facility staff are knowledgeable about the problems and needs of the aged, ill, and disabled.				
F101	2. Facility staff practices proper techniques in providing care to the aged, ill, and disabled.				
F102	3. Facility staff practice proper technique for prevention and control of infection, fire prevention and safety, accident prevention, confidentiality of resident information, and preservation of resident dignity, including protection of privacy and personal and property rights.				
F103	**STATUS CHANGE NOTIFICATIONS** SNF (405.1121(j)) (Standard) ☐ MET ☐ NOT MET				
F104	ICF (442.307) (Standard) ☐ Met ☐ Not Met				
F105	1. The facility notifies the resident's attending physician and other responsible persons in the event of an accident involving the resident, or other significant change in the resident's physical, mental, or emotional status, or resident charges, billings, and related administrative matters.				
F106	2. Except in a medical emergency, a resident is not transferred or discharged, nor is treatment altered radically, without consultation with the resident or, if the resident is incompetent, without prior notification of next of kin or sponsor.				

NAME OF FACILITY

CODE	PHYSICIANS' SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	PHYSICIANS' SERVICES *(CONDITION OF PARTICIPATION)*				
F107	SNF (405.1123) ☐ MET ☐ NOT MET				
	A. Medical Findings and Orders at Time of Admission				
F108	SNF (405.1123(a)) (Standard) ☐ MET ☐ NOT MET				
F109	1. There is made available to the facility prior to or at the time of admission, resident information which includes current medical findings, diagnoses, and orders from a physician for immediate care of the resident.				
F110	2. Information about the rehabilitation potential of the resident and a summary of prior treatment are made available to the facility at the time of admission or within 48 hours thereafter.				

NAME OF FACILITY

CODE	PHYSICIANS' SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	B. Resident Supervision by Physician				
F111	SNF (405.1123(b)) (Standard) ☐ MET ☐ NOT MET				
F112	ICF (442.346) (Standard) ☐ MET ☐ NOT MET **Indicators B and C apply to** this standard for ICFs				
F113	1. Every resident must be under the supervision of a physician.				
F114	2. A physician prescribes a planned regimen of care based on a medical evaluation of each resident's immediate and long-term care needs. **Exception: Not required for ICF residents**				
F115	3. A physician is available to provide care in the absence of any resident's attending physician.				
F116	4. Medical evaluation is done within 48 hours of admission unless done within 5 days prior to admission. **Exception: Not required for ICF residents.**				
F117	5. Each resident is seen by their attending physician at least once every 30 days for the first 90 days after admission. **Exception: ICF residents must be seen every 60 days unless otherwise justified and documented by the attending physician.**				
F118	6. Each resident's total program of care including medications and treatments is reviewed during a visit by the attending physician at least once every 30 days for the first 90 days and revised as necessary. **Exception: Only medications must be reviewed quarterly for ICF residents.**				

NAME OF FACILITY

CODE	PHYSICIANS' SERVICES/NURSING SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
F119	7. Progress notes are written and signed by the physician at the time of each visit, and all orders are signed by the physician.				
F120	8. Alternate physician visit schedules that exceed a 30-day schedule adopted after the 90th day following admission are justified by the attending physician in the medical record. These visits cannot exceed 60 days or apply to residents who require specialized rehabilitation schedules. EXCEPTION: Not required for ICF residents.				
F121	C. **Emergency Services** SNF (405.1123(c)) (Standard) ☐ MET ☐ NOT MET				
F122	Emergency services from a physician are available and provided to each resident who requires emergency care.				
F123	**NURSING SERVICES *(CONDITION OF PARTICIPATION)*** SNF (405.1124) ☐ MET ☐ NOT MET				
F124	SNF (405.1124(c)) (Standard) ☐ Met ☐ Not Met Indicators A and B apply to this standard for SNFs.				
F125	ICF (442.338) ☐ Met ☐ Not Met Indicators A thru E apply to this standard for ICFs except where noted.				
	A. The facility provides nursing services which are sufficient to meet nursing needs of all residents all hours of each day.				
F126	1. Each resident receives all treatments, medications and diet as prescribed. Deviations are reported and appropriate action is taken.				

NAME OF FACILITY

CODE	NURSING SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
F127	2. Each resident receives daily personal hygiene as needed to assure cleanliness, good skin care, good grooming, and oral hygiene taking into account individual preferences. Residents are encouraged to engage in self care activity.				
F128	3. Each resident receives care necessary to prevent skin breakdown.				
F129	4. Each resident with a decubitus receives care necessary to promote the healing of the decubitus including proper dressing.				
F130	5. When residents require restraints the application is ordered by the physician, applied properly, and released at least every 2 hours.				
F131	6. Each resident with incontinence is provided with care necessary to encourage continence including frequent toileting and opportunities for rehabilitative training.				
F132	7. Each resident with a urinary catheter receives proper routine care including periodic evaluation.				
F133	8. Each resident receives proper care for the following needs: Injections Parenteral Fluids Colostomy/Ileostomy Respiratory Care Tracheostomy Care Suctioning Tube Feeding				
F134	9. Infection Control Techniques are properly carried out in the provision of care to each resident.				

Form HCFA-519 (8-88)

NAME OF FACILITY

CODE	NURSING SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
F135	10. Proper nursing and sanitary procedures and techniques are used when medications are given to residents.			▨	
F136	11. Adequate resident care supplies are available for providing treatments.			▨	
	B. Twenty-Four Hour Nursing Service				
F137	1. **Nursing personnel, including registered nurses, licensed practical (vocational) nurses, nurse aides, orderlies, and ward clerks, are assigned duties consistent with their education and experience, and based on the characteristics of the resident load.** EXCEPTION: Not required for ICFs.				
F138	2. **Weekly time schedules are maintained and indicate the number and classifications of nursing personnel including relief personnel, who worked on each unit for each tour of duty.** **(If a distinct part certification, show the staffing for the DP and, if appropriate, any nonparticipating remainder and explain any sharing of nursing personnel.)** **Exception: Not required for Freestanding ICFs.**				
F139	3. **There is a sufficient number of nursing staff available to meet the total needs of all residents.**			▨	
F140	4. **There is a registered nurse on the day tour of duty 7 days a week.** **Exception: Not required for ICF residents.**				

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NAME OF FACILITY

CODE	NURSING SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
F141	C. **Charge Nurse** SNF (405.1124(b)) (Standard) ☐ MET ☐ NOT MET				
F142	1. A **registered** nurse or a qualified licensed practical (or vocational) nurse is designated as charge nurse by the director of nursing for each tour of duty. **Exception: Not required for ICFs.**				
F143	2. The director of nursing services does not serve as charge nurse in a facility with an average daily total occupancy of 60 or more residents. **Exception: Not required for ICFs.**				
F144	3. The ICF must have a registered nurse, or a licensed practical or vocational nurse full-time, 7 days a week, on the day shift. **Exception: Not required for SNFs.**				

Form HCFA-519 (9-86)

NAME OF FACILITY

List the number of full-time equivalents of RN's, LPN's, Aides/Orderlies assigned to nursing duty from the last 3 complete weeks. (Note only actual staff on duty.)

Shift		CODE	Day 1			Day 2			Day 3			Day 4			Day 5			Day 6			Day 7		
			RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A
DAY	DP	F145																					
	Entire Facility	F146																					
EVENING	DP	F147																					
	Entire Facility	F148																					
NIGHT	DP	F149																					
	Entire Facility	F150																					

Shift		CODE	Day 1			Day 2			Day 3			Day 4			Day 5			Day 6			Day 7		
			RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A
DAY	DP																						
	Entire Facility																						
EVENING	DP																						
	Entire Facility																						
NIGHT	DP																						
	Entire Facility																						

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NAME OF FACILITY

Shift		CODE	Day 1			Day 2			Day 3			Day 4			Day 5			Day 6			Day 7		
			RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A
DAY	DP	F151																					
	Entire Facility	F152																					
EVENING	DP	F153																					
	Entire Facility	F154																					
NIGHT	DP	F155																					
	Entire Facility	F156																					

STAFFING PATTERN WORKSHEETS DAY OF SURVEY (OPTIONAL)

ENTIRE FACILITY STAFFING PATTERN (DAY OF SURVEY)

	CODE		RN	PN	A
DAY	F157	REPORT			
	F158	ACTUAL			
EVENING	F159	REPORT			
	F160	ACTUAL			
NIGHT	F161	REPORT			
	F162	ACTUAL			

UNIT STAFFING PATTERN WORKSHEET (DAY OF SURVEY)

	CODE	Unit			Unit			Unit			Unit			Unit			Unit			Unit		
		RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A
DAY	F163																					
EVENING	F164																					
NIGHT	F165																					
CENSUS	F166																					

NAME OF FACILITY

CODE	NURSING SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	D PATIENT CARE MANAGEMENT				
F167	SNF (405.1124(d)) (Standard) ☐ MET ☐ NOT MET				
F168	ICF (442.341) (Standard) ☐ MET ☐ NOT MET				
F169	1 Each resident's needs are addressed in a written plan of care which demonstrates that the plans of all services are integrated, consonant with the physician's plan of medical care, and implemented shortly after admission.				
F170	2 Each professional service identifies needs, goals, plans, and evaluates the effectiveness of interventions, plus institutes changes in the plan of care in a timely manner.				
	E. Rehabilitative Nursing Services are performed daily, and recorded for those residents who require such service.				
F171	SNF (405.1124(e)) (Standard) ☐ MET ☐ NOT MET				
F172	ICF (442.342) (Standard) ☐ Met ☐ Not Met				
F173	1. Each resident receives rehabilitative nursing care to promote maximum physical functioning to prevent immobility, deformities, and contractures.				
F174	2. There is an ongoing evaluation of each resident's rehabilitative nursing needs. This may include;				
F175	(a) Range of motion, ambulation, turning and positioning and other activities;				
F176	(b) Assistance and instruction in the activities of daily living such as feeding, dressing, grooming, oral hygiene and toilet activities;				
F177	(c) Remotivation therapy and/or reality orientation when appropriate.				
F178	3. These activities are coordinated with other resident care services				

Form HCFA-519 (2-86)

NAME OF FACILITY

CODE	NURSING SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
F179	F. **The facility has an awareness of nutritional needs and fluid intake of residents and provides prompt assistance where necessary in feeding residents.** SNF (405.1124(f)) (Standard) ☐ MET ☐ NOT MET				
F180	1. Each resident is provided with the amount of food and fluid on a daily basis necessary to maintain their appropriate minimum average weight. Between meal feedings are offered and the amount consumed is observed. Daily food and fluid intake is observed and encouraged.				
F181	2. Each resident needing assistance in eating or drinking is provided prompt assistance. Specific self-help devices are available when necessary.				
F182	3. Deviations from normal food and fluid intake are recorded and reported to the charge nurse and the attending physician.				

NAME OF FACILITY

CODE	NURSING SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
F183	G. **Administration of Drugs** SNF (405.1124(g)) (Standard) ☐ MET ☐ NOT MET				
F184	ICF (442.337) (Standard) ☐ MET ☐ NOT MET				
F185	1. The resident is identified prior to administration of a drug.				
F186	2. Drugs and biologicals are administered as soon as possible after doses are prepared.				
F187	3. Administered by same person who prepared the doses for administration except under single unit dose package distribution systems.				
F188	Exception: ICF residents may self administer medication only with their physician's permission.				
	H. **Conformance with Physician Drug Orders**				
F189	SNF (405.1124(h)) (Standard) ☐ MET ☐ NOT MET				
F190	ICF (442.334) (Standard) ☐ MET ☐ NOT MET				
F191	Drugs are administered in accordance with written orders of the attending physician.				
F192	Drug Error Rate ________ % (See Form HCFA-522)				

Form HCFA-519 (2-86)

NAME OF FACILITY

CODE	DIETETIC SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	DIETETIC SERVICES *(CONDITION OF PARTICIPATION)*				
F193	SNF (405.1125) ☐ MET ☐ NOT MET				
F194	ICF (442.332) (Standard) ☐ MET ☐ NOT MET Indicators A and B apply to this standard for ICFs.				
	A. **Menus and Nutritional Adequacy**				
F195	SNF (405.1125(b)) (Standard) ☐ MET ☐ NOT MET				
F196	Menus are planned and followed to meet the nutritional needs of each resident in accordance with physicians' orders and, to the extent medically possible, based on the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences.				
	B. **Therapeutic Diets**				
F197	SNF (405.1125(c)) (Standard) ☐ MET ☐ NOT MET				
F198	1. Therapeutic diets are prescribed by the attending physician.				
F199	2. Therapeutic menus are planned in writing, prepared, and served as ordered with supervision from the dietitian and advice from the physician whenever necessary.				
F200	Number of Regular Diets________				
F201	Number of Therapeutic Diets________				
F202	Number of Mechanically Altered Diets ________				
F203	Number of Tube Feedings________				

NAME OF FACILITY

CODE	DIETETIC SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
F204	**C. Preparation** SNF (405.1125(e)) (Standard) ☐ MET ☐ NOT MET				
F205	1. Food is prepared by methods that conserve its nutritive value and flavor.				
F206	2. Meals are palatable, served at proper temperatures. They are cut, ground, chopped, pureed or in a form which meets individual resident needs.				
F207	3. If a resident refuses food served, appropriate substitutes of similar nutritive value are offered.				
F208	**D. Frequency** SNF (405.1125(d)) (Standard) ☐ MET ☐ NOT MET				
F209	ICF (442.331) (Standard) ☐ MET ☐ NOT MET				
F210	1. At least three meals are served daily at regular hours with not more than a 14-hour span between a substantial evening meal and breakfast.				
F211	2. To the extent medically possible, bedtime nourishments are offered to all residents. Exception: Not required for ICF Residents.				
F212	**E. Staffing** SNF (405.1125(a)) (Standard) ☐ MET ☐ NOT MET				
F213	1. Food service personnel are on duty daily over a period of 12 or more hours.				

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NAME OF FACILITY

CODE	SPECIALIZED REHABILITATIVE SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	SPECIALIZED REHABILITATIVE SERVICES *(CONDITION OF PARTICIPATION)*				
F214	SNF (405.1126) ☐ MET ☐ NOT MET				
F215	SNF (405.1126(b)) (Standard) ☐ MET ☐ NOT MET				
F216	ICF (442.343) (Standard) ☐ MET ☐ NOT MET				
	A. **Plan of Care**				
F217	Rehabilitative services are provided under a written plan of care, initiated by the attending physician and developed in consultation with appropriate therapists(s) and the nursing service.				
	B. **Therapy**				
F218	Therapy is provided according to orders of the attending physician in accordance with accepted professional practices by qualified therapists or qualified assistants.				
	C. **Progress**				
F219	1. **A report of the resident's progress is communicated to the attending physician within 2 weeks of the initiation of specialized rehabilitative services.** **Exception: ICF resident's progress must be reviewed regularly.**				

NAME OF FACILITY

CODE	SPECIALIZED REHABILITATIVE SERVICES/PHARMACEUTICAL SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
F220	2. The resident's progress is thereafter reviewed regularly, and the plan of rehabilitative care is reevaluated as necessary, but at least every 30 days, by the physician and the therapist. **Exceptions: ICF residents' plans must be revised as necessary.**				
F221	**PHARMACEUTICAL SERVICES *(CONDITION OF PARTICIPATION)*** SNF (405.1127) ☐ MET ☐ NOT MET				
F222	**A. Supervision** SNF (405.1127(a)) (Standard) ☐ MET ☐ NOT MET				
F223	ICF (442.336) (Standard) ☐ MET ☐ NOT MET				
F224	The pharmacist reviews the drug regimen of each resident at least monthly and reports any irregularities to the medical director and administrator.				

NAME OF FACILITY

CODE	PHARMACEUTICAL SERVICES LABORATORY AND RADIOLOGIC SERVICES/SOCIAL SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	B. Labeling of Drugs and Biologicals				
F225	SNF (405.1127(c)) (Standard) ☐ MET ☐ NOT MET				
F226	ICF (442.333) (Standard) ☐ MET ☐ NOT MET				
F227	The labeling of drugs and biologicals is based on currently accepted professional principles and includes the appropriate accessary and cautionary instructions as well as an expiration date when applicable.				
	LABORATORY AND RADIOLOGIC SERVICES *(CONDITION OF PARTICIPATION)*				
F228	SNF (405.1128) ☐ MET ☐ NOT MET				
F229	SNF (405.1128(a)) (Standard) ☐ MET ☐ NOT MET				
	Provision of Services				
F230	1. All services are provided only on the orders of a physician.				
F231	2. The attending physician is notified promptly of diagnostic findings.				
F232	3. Signed and dated reports of a clinical laboratory, X-ray and other diagnostic services are filed with the resident's medical record.				

NAME OF FACILITY

CODE	SOCIAL SERVICES/ACTIVITIES	YES	NO	N/A	EXPLANATORY STATEMENT
	SOCIAL SERVICES *(CONDITION OF PARTICIPATION)*				
F233	SNF (405.1130) ☐ MET ☐ NOT MET				
F234	SNF (405.1130(a)) (Standard) ☐ MET ☐ NOT MET				
F235	ICF (442.344) (Standard) ☐ MET ☐ NOT MET				
	A. **Plan**				
F236	The medically related social and emotional needs of the resident are identified.				
	B. **Provision of Services**				
F237	1. Services are provided to meet the social and emotional needs by the facility or by referral to an appropriate social agency				
F238	2. If financial assistance is indicated, arrangements are made promptly for referral to an appropriate agency				
	ACTIVITIES *(CONDITION OF PARTICIPATION)*				
F239	SNF(405.1131) ☐ MET ☐ NOT MET				
	Provision of Services				
F240	SNF (405.1131(b)) (Standard) ☐ MET ☐ NOT MET				

NAME OF FACILITY

CODE	ACTIVITIES	YES	NO	N/A	EXPLANATORY STATEMENT
F241	ICF (442.345) (Standard) ☐ MET ☐ NOT MET				
F242	1. An ongoing program of meaningful activities is provided based on identified needs and interests of each resident. It is designed to promote opportunities for engaging in normal pursuits, including religious activities of their choice, if any.				
F243	2. Unless contraindicated by the attending physicians each resident is encouraged to participate in the activities program.				
F244	3. The activities promote the physical, social and mental well-being of the resident.				
F245	4. Equipment is maintained in good working order.				
F246	5. Supplies and equipment are available.				

NAME OF FACILITY

CODE	MEDICAL RECORDS	YES	NO	N/A	EXPLANATORY STATEMENT
	MEDICAL RECORDS *(CONDITION OF PARTICIPATION)*				
F247	SNF (405.1132) ☐ MET ☐ NOT MET				
	Content				
F248	SNF (405.1132(c)) (Standard) ☐ MET ☐ NOT MET				
F249	ICF (442.318) (Standard) ☐ MET ☐ NOT MET				
F250	1. The medical record contains sufficient information to identify the resident clearly, to justify diagnoses and treatment, and to document results accurately.				

NAME OF FACILITY

CODE	MEDICAL RECORDS	YES	NO	N/A	EXPLANATORY STATEMENT
	2. The medical record contains the following information:				
F251	a. Identification information				
F252	b. Admission data including past medical and social history				
F253	c. Transfer form, discharge summary from any transferring facility				
F254	d. Report of resident's attending physician				
F255	e. Report of physical examinations				
F256	f. Reports of physicians' periodic evaluations and progress notes				
F257	g. Diagnostic reports and therapeutic orders				
F258	h. Reports of treatments				
F259	i. Medications administered				
F260	j. An overall plan of care setting forth goals to be accomplished through each service's designed activities, therapies and treatments.				
F261	k. Assessments and goals of each service's plan of care				
F262	l. Treatments and services rendered				
F263	m. Progress notes				
F264	n. All symptoms and other indications of illness or injury including date, time and action taken regarding each problem.				

NAME OF FACILITY

CODE		YES	NO	N/A	EXPLANATORY STATEMENT
	TRANSFER AGREEMENT *(CONDITION OF PARTICIPATION)*				
F265	SNF (405.1133) ☐ MET ☐ NOT MET				
F266	SNF (405.1133(a)) (Standard) ☐ MET ☐ NOT MET				
F267	ICF (442.316) (Standard) ☐ MET ☐ NOT MET				
F268	A. Whenever the attending physician determines that a transfer is medically appropriate between a hospital or a facility providing more specialized care and the nursing facility, admission to the new facility shall be effected in a timely manner.				
F269	B. Information necessary for providing care and treatment to transferred individuals is provided.				

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NAME OF FACILITY

CODE	PHYSICAL ENVIRONMENT	YES	NO	N/A	EXPLANATORY STATEMENT
	PHYSICAL ENVIRONMENT *(CONDITION OF PARTICIPATION)*				
F270	SNF (405.1134) ☐ MET ☐ NOT MET				
	A. **Nursing Unit**				
F271	SNF (405.1134(d)) (Standard) ☐ MET ☐ NOT MET				
F272	1. The unit is properly equipped for preparation and storage of drugs and biologicals.				
F273	2. Utility and storage rooms are adequate in size.				
F274	3. The unit is equipped to register resident calls with a functioning communication system from resident areas including resident rooms and toilet and bathing facilities.				
	B. **Dining and Activities Area**				
F275	SNF (405.1134(g) (Standard) ☐ MET ☐ NOT MET				
F276	ICF (442.329) (Standard) ☐ MET ☐ NOT MET				
F277	1. The facility provides one or more clean, orderly and appropriately furnished rooms of adequate size, designated for resident dining and resident activities.				
F278	2. Dining and activity rooms are well lighted and ventilated.				
F279	3. Any multipurpose room used for dining and resident activities has sufficient space to accommodate all activities and prevent their interference with each other.				

NAME OF FACILITY

CODE	PHYSICAL ENVIRONMENT	YES	NO	N/A	EXPLANATORY STATEMENT
F280	SNF (405.1134(e)) (Standard) ☐ MET ☐ NOT MET INDICATORS C AND D APPLY TO THIS STANDARD FOR SNFS.				
F281	**C. Resident Rooms** ICF (442.325) (Standard) ☐ MET ☐ NOT MET				
F282	1. Single resident rooms have at least 100 square feet.				
F283	2. Multiple resident rooms have no more than four residents and at least 80 square feet per resident.				
F284	3. Each room is equipped with or conveniently located near toilet and bathing facilities.				
F285	4. There is capability of maintaining privacy in each.				
F286	5. There is adequate storage space for each resident.				
F287	6. There is a comfortable and functioning bed and chair plus a functional cabinet and light.				
F288	7. The resident call system functions in resident rooms.				
F289	8. Each room is designed and equipped for adequate nursing care and the comfort and privacy of the residents.				
F290	9. Each room is at or above grade level.				
F291	10. Each room has direct access to a corridor and outside exposure. **Exception: Not required for ICF residents.**				

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NAME OF FACILITY

CODE	PHYSICAL ENVIRONMENT	YES	NO	N/A	EXPLANATORY STATEMENT
F292	D. **Toilet and Bath Facilities** ICF (442.326) (Standard) ☐ MET ☐ NOT MET				
F293	1. Facilities are clean, sanitary and free of odors.				
F294	2. Facilities have safe and comfortable hot water temperatures.				
F295	3. Facilities maintain privacy.				
F296	4. Facilities have grab bars and other safeguards against slipping.				
F297	5. Facilities have fixtures in good condition.				
F298	6. The resident call system functions in toilet and bath facilities.				
F299	E. **Social Service Area** SNF (405.1130(b)) (Standard) ☐ MET ☐ NOT MET				
F300	1. Ensures privacy for social service interviewing.				
F301	2. Adequate space for clerical and interviewing functions is provided.				
F302	3. Facilities are easily acessible to residents and staff.				

NAME OF FACILITY

CODE	PHYSICAL ENVIRONMENT	YES	NO	N/A	EXPLANATORY STATEMENT
	F. **Therapy Areas**				
F303	SNF (405.1126(a)) (Standard) ☐ MET ☐ NOT MET				
F304	ICF (442.328(a)) ☐ MET ☐ NOT MET				
F305	1. Space is adequate for proper use of equipment by all residents receiving treatments.				
F306	2. Equipment is safe and in proper working condition.				
	G. **Facilities for Special Care**				
F307	SNF (405.1134(f)) (Standard) ☐ MET ☐ NOT MET				
F308	ICF (442.328(b)) ☐ MET ☐ NOT MET				
F309	1. Single rooms with private toilet and handwashing facilities are available for isolating residents.				
F310	2. Precautionary signs are used to identify these rooms when in use.				
	H. **Common Resident Areas**				
F311	SNF (405.1134(j)) (Standard) ☐ MET ☐ NOT MET				
F312	ICF (442.324) (Standard) ☐ MET ☐ NOT MET				
F313	1. All common resident areas are clean, sanitary and free of odors.				
F314	2. Provision is made for adequate and comfortable lighting levels in all areas.				
F315	3. There is limitation of sounds at comfort levels.				

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Page 31

NAME OF FACILITY

CODE	PHYSICAL ENVIRONMENT	YES	NO	N/A	EXPLANATORY STATEMENT
F316	4. A comfortable room temperature is maintained.				
F317	5. There is adequate ventilation through windows or mechanical means or a combination of both.				
F318	6. Corridors are equipped with firmly secured handrails on each side.				
F319	7. Staff are aware of procedures to ensure water to all essential areas in the event of loss of normal supply.				
	I. Maintenance of Building and Equipment				
F320	SNF (405.1134(i)) (Standard) ☐ MET ☐ NOT MET				
F321	1. The interior and exterior of the building are clean and orderly.				
F322	2. All essential mechanical and electrical equipment is maintained in safe operating condition.				
F323	3. Sufficient storage space is available and used for equipment to ensure that the facility is orderly and safe.				
F324	4. Resident care equipment is clean and maintained in safe operating condition.				
F325	ICF (442.331(b)) ☐ MET ☐ NOT MET Indicators J thru L apply to ICFs.				
	J. Dietetic Service Area				
F326	SNF (405.1134(h)) (Standard) ☐ MET ☐ NOT MET				
F327	1. Kitchen and dietetic service areas are adequate to insure proper, timely food services for all residents				
F328	2. Kitchen areas are properly ventilated, arranged, and equipped for storage and preparation of food as well as for dish and utensil cleaning, and refuse storage and removal.				

NAME OF FACILITY

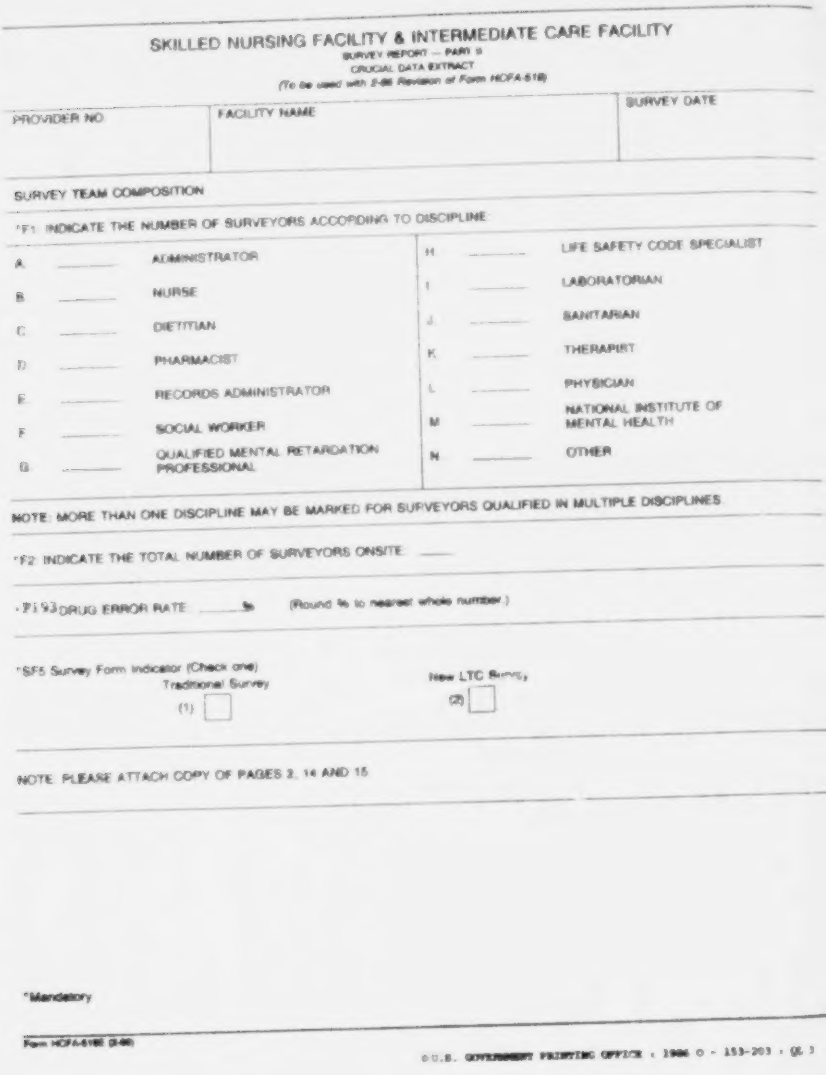
CODE	PHYSICAL ENVIRONMENT/INFECTION CONTROL	YES	NC	N/A	EXPLANATORY STATEMENT
	K. HYGIENE OF DIETARY STAFF				
F329	SNF (405.1125(f)) (Standard) ☐ Met ☐ Not Met				
F330	Dietetic service personnel practice hygienic food handling techniques.				
	L. DIETARY SANITARY CONDITIONS				
F331	SNF (405.1125(g)) (Standard) ☐ Met ☐ Not Met				
F332	1. Food is stored, refrigerated, prepared, distributed, and served under sanitary conditions.				
F333	2. Waste is disposed of properly.				
	M. Emergency Power				
F334	**SNF (405.1134(b))** (Standard) ☐ **MET** ☐ **NOT MET**				
F335	1. An emergency source of electrical power necessary to protect the health and safety of residents is available in the event the normal electrical supply is interrupted.				
F336	2. Emergency power is adequate at least for lighting in all means of egress; equipment to maintain fire detection, alarm, and extinguishing systems; and life safety support systems.				
F337	3. Emergency power is provided by an emergency electrical generator located on the premises where life support systems are used.				
	INFECTION CONTROL *(CONDITION OF PARTICIPATION)*				
F338	SNF (405.1135) ☐ MET ☐ NOT MET				
	A. Infection Control				
F339	SNF (405.1135(b)) (Standard) ☐ MET ☐ NOT MET				
F340	Aseptic and isolation techniques are followed by all personnel.				

NAME OF FACILITY

CODE	INFECTION CONTROL/DISASTER PREPAREDNESS	YES	NO	N/A	EXPLANATORY STATEMENT
	B. Sanitation				
F341	SNF (405.1135(c)) (Standard) ☐ MET ☐ NOT MET				
F342	The facility maintains a safe, clean, and orderly interior.				
	C. Linen				
F343	SNF (405.1135(d) (Standard) ☐ MET ☐ NOT MET				
F344	ICF (442.327) (Standard) ☐ MET ☐ NOT MET				
F345	1. The facility has available at all times a quantity of linen essential for proper care and comfort of residents.				
F346	2. Linens are handled; stored, processed, and transported in such a manner as to prevent the spread of infection.				
	D. PEST CONTROL				
F347	SNF (405.1135(e)) (Standard) ☐ Met ☐ Not Met				
F348	ICF (442.315(c)) (Standard) ☐ Met ☐ Not Met				
F349	The facility is maintained free from insects and rodents.				
	DISASTER PREPAREDNESS *(CONDITION OF PARTICIPATION)*				
F350	SNF (405.1136) ☐ MET ☐ NOT MET				
F351	SNF (405.1136(a)) (Standard) ☐ MET ☐ NOT MET				
F352	ICF (442.313) (Standard) ☐ MET ☐ NOT MET Indicators A and B apply to this standard for ICFs.				
	A. Disaster Plan				
F353	1. Facility staff are aware of plans, procedures to be followed for fire, explosion or other disaster.				

NAME OF FACILITY

CODE	DISASTER PREPAREDNESS	YES	NO	N/A	EXPLANATORY STATEMENT
F354	2. Facility staff are knowledgeable about evacuation routes.				
F355	3. Facility staff are aware of their specific responsibilities in regard to evaluation and protection of residents.				
F356	4. Facility staff are aware of methods of containing fire.				
	B. Drills				
F357	SNF (405.1136(b)) (Standard) ☐ MET ☐ NOT MET				
F358	1. All employees are trained, as part of their employment orientation in all aspects of preparedness for any disaster.				
F359	2. Facility staff participate in ongoing training and drills in all procedures so that each employee promptly and correctly carries out a specific role in case of a disaster.				



SKILLED NURSING FACILITY & INTERMEDIATE CARE FACILITY
SURVEY REPORT — PART II
CRUCIAL DATA EXTRACT
(To be used with 2-86 Revision of Form HCFA-519)

PROVIDER NO	FACILITY NAME	SURVEY DATE

SURVEY TEAM COMPOSITION

*F1 INDICATE THE NUMBER OF SURVEYORS ACCORDING TO DISCIPLINE:

A	______	ADMINISTRATOR	H	______	LIFE SAFETY CODE SPECIALIST
B	______	NURSE	I	______	LABORATORIAN
C	______	DIETITIAN	J	______	SANITARIAN
D	______	PHARMACIST	K	______	THERAPIST
E	______	RECORDS ADMINISTRATOR	L	______	PHYSICIAN
F	______	SOCIAL WORKER	M	______	NATIONAL INSTITUTE OF MENTAL HEALTH
G	______	QUALIFIED MENTAL RETARDATION PROFESSIONAL	N	______	OTHER

NOTE: MORE THAN ONE DISCIPLINE MAY BE MARKED FOR SURVEYORS QUALIFIED IN MULTIPLE DISCIPLINES.

*F2 INDICATE THE TOTAL NUMBER OF SURVEYORS ONSITE ____

*F193 DRUG ERROR RATE ____% (Round % to nearest whole number.)

*SF5 Survey Form Indicator (Check one)

Traditional Survey (1) ☐

New LTC Survey (2) ☐

NOTE: PLEASE ATTACH COPY OF PAGES 2, 14 AND 15

*Mandatory

Form HCFA-519E (2-86)

☆U.S. GOVERNMENT PRINTING OFFICE : 1986 O - 153-203 : QL 3

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO. 0938-0400

RESIDENTS SELECTED FOR INDEPTH REVIEW

PROVIDER NUMBER	SURVEY DATE

	RESIDENT NAME (TARGETED)*	ROOM NUMBER	REASON FOR SELECTION
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			

FORM HCFA-520 (2-88)

* NOTE IF ICF OR SNF RESIDENT

☆ U.S. GPO 1988-0-181-[illegible]

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO. 0938-0400

TOUR NOTES WORKSHEET

PROVIDER NUMBER

SURVEY DATE

INSTRUCTIONS

1 Note care and problems in care on all units.
2 Report deficiencies directly to survey report form or evaluate further during indepth sample review.
3 Select residents for indepth review.
4 Select a proportionate number from each section.

INDEPTH SAMPLE

Facility Census	0-60	61-120	121-200	200+
Sample Size	25% (Min10)	20% (Min15)	15% (Min26)	10% (Min30) (Max50)

OBSERVE RESIDENTS FOR THE FOLLOWING CARE PROBLEMS

GROOMING/PERSONAL HYGIENE

POSITIONING

ASSISTIVE DEVICES

AMBULATION

RESTRAINTS

HYDRATION

INFECTION CONTROL

PATIENT RIGHTS

OTHER

[illegible]

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO. 0938-0400

OBSERVATION / INTERVIEW RECORD REVIEW WORKSHEET

PROVIDER NUMBER	SURVEY DATE	OBSERVATION/INTERVIEW OF: (RESIDENT IDENTIFIER)

INSTRUCTIONS

1. Observe each resident in sample to identify ADL needs and potential problems. Check appropriate blocks.
2. Interview only residents in sample who are capable and willing.
3. Review each resident's record to ensure assessments, plans, interventions and evaluations are appropriate and current.
4. Note deficiencies on survey report form after reviewing all residents in sample.

RESIDENT NEEDS

ADL's
☐ Bathing
☐ Dressing
☐ Toileting
☐ Transferring
☐ Continence
☐ Feeding

SKIN
☐ Tears/Wounds
☐ Ulcers
☐ Rashes
☐ Flaking
☐ Scaling
☐ Red Area

DECUBITUS
☐ Grade
☐ Foul Odor
☐ Draining
☐ Dressing
☐ Unclean
☐ Not Dry
☐ Not Intact
☐ Poor Technique

GROOMING/HYGIENE
☐ Eyes/Ears/Mouth
☐ Oral/Dental Hygiene
☐ Foot Care
☐ Facial Hair
☐ Hair/Scalp
☐ Nails
☐ Clothing
☐ Shoes/Slippers
☐ Odors

POSITIONING
☐ Need Present
☐ Contracted Extremities
☐ Improper Position
☐ No Protective Device
☐ ROM Improper
☐ Lack of Turning as Needed
☐ Schedule Not Present
☐ Improper Techniques
☐ Aseptic/Other

DRESSINGS
☐ Present
☐ Unclean
☐ Not Dry
☐ Not Intact
☐ Foul Odor
☐ Poor Technique

RESTRAINTS
☐ Type
☐ Inappropriate Application
☐ Improper Body Alignment/Support
☐ Not Released/Exercised Every 2 Hours
☐ Chemically Restrained

BOWEL/BLADDER
☐ Incontinent
☐ Not Routinely Toileted
☐ Commode Not Available
☐ Schedule Not Available

CATHETER
☐ Present
☐ Inappropriate
☐ Poor Drainage
☐ Drainage System Open
☐ No Urine in Bag
☐ Urine Leaking
☐ Abdomen Distended
☐ Tubing Not Clean
☐ No I/O Recording
☐ Supply Storage Unclean

INJECTIONS
☐ Receives Injections
☐ Site Red/Swollen
☐ Improper Technique
☐ Resident Reacts

COLOSTOMY/ILEOSTOMY
☐ Present
☐ Not Well Regulated
☐ Odors
☐ Diarrhea/Constipation
☐ Site Red/Irritated

PARENTERAL FLUID/IV'S
☐ Present
☐ Rate Incorrect/Stopped
☐ Site Red/Swollen
☐ Dressing Unclean
☐ Unsafe Splint
☐ Improper Label
☐ Outdated Solution
☐ No I/O Recording

TRACHEOSOTOMY
☐ Present
☐ Site Red/Swollen
☐ Obstructed
☐ Unclean
☐ Improper Suctioning
☐ Equipment Not Available

SUCTIONING
☐ Need Present
☐ Audible Rales
☐ Labored Breathing
☐ Drainage
☐ Equipment Not Available

RESPIRATORY
☐ Congested/Short Breath
☐ IPPB Not Available
☐ Oxygen Not Available
☐ Improper Equipment Use

DIETARY NEEDS
☐ Over/Underweight
☐ Dehydrated
☐ Edema
☐ Emaciated
☐ Dull/Dry Hair
☐ Swollen/Red Tongue
☐ Bleeding Gums
☐ Cracked Lips
☐ Inability to Chew
☐ Swallowing Prob.
☐ Pallor

TUBE FEEDING
☐ Present
☐ Nutrition Inadequate
☐ Poorly Tolerated
☐ Vomits
☐ Dehydrated
☐ Over/Underweight
☐ Diarrhea/Constipation
☐ Poor Skin Condition
☐ Poor Mouth Condition
☐ Improper Technique

REHABILITATION NEEDS
☐ Cannot Communicate
☐ Ineffective Use of Assistive Device
☐ Improper Equipment Use
☐ Improper Technique
☐ Equipment Inadequate

SOCIAL SERVICE NEEDS
☐ Not Oriented
☐ Not Able to Converse
☐ Uncooperative/Disrupts
☐ Withdrawn
☐ Anxious
☐ Confused
☐ Lonely
☐ Vision/Hearing Needs
☐ Mentally Retarded

OTHER
☐
☐
☐
☐
☐

ACTIVITY NEEDS
☐ Not Participating
☐ Vision/Hearing
☐ Chair/Bedfast
☐ Dependence ≥4 ADL's

PATIENT RIGHTS
☐ Privacy Not Maintained
☐ Staff Not Courteous
☐ Not Informed of Rights
☐ Mental/Physical Abuse
☐ Cannot Exercise Rights
☐ Cannot Manage Affairs

NOTES

Form HCFA 524 (2-86)

SEE REVERSE

RECORD REVIEW

☐ Drug Regimen Review (See SOM Appendix N Part 1)
☐ Satisfactory ☐ Unsatisfactory

ROUTINE REPORTS: ☐ Weights ☐ Lab ☐ X-ray ☐ Other

ASSESSMENT	PLAN	INTERVENTION	EVALUATION

PHYSICIAN SERVICES

☐ Admission Information
☐ Rehabilitation Information
☐ Physical Exam
☐ Written Care Plan
☐ Signs Orders/Notes
☐ Required Visits
☐ Emergency Availability
☐ Review of Care

U.S. GPO [illegible]-0-161-[illegible]

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO. 0938-0400

DRUG PASS WORKSHEET

PROVIDER NUMBER

SURVEY DATE

ERROR RATE ☐

INSTRUCTIONS	DEFICIENCY FORMULA
1 Perform Drug Pass Observations on 20 Residents 2 Record Observation of each Opportunity 3 Compare Observation Notes with Physician Orders 4 Calculate and Note Error Rate 5 Note Deficiencies on Survey Report Form	1 One or more Significant Errors = Deficiency 2 $\frac{\text{Significant + Non-significant}}{\text{Doses Given + Doses Ordered But Not Given}} \times 100 \quad \geq 5\% = \text{Deficiency}$

IDENTIFIER	POUR	PASS	RECORD
RESIDENT'S FULL NAME, ROOM NUMBER, TIME	DRUG PRESCRIPTION NAME, DOSE AND FORM	OBSERVATION OF ADMINISTRATION	DRUG ORDER WRITTEN AS (IF DIFFERS FROM ADMINIS ONLY)

FORM HCFA-522 (2-86)

SEE REVERSE

DRUG ERROR CALCULATION
(SEE SOM Appendix N Part 2)

How to Calculate a Medication Error Rate—In calculating the percentage of errors, the numerator in the ratio is the total number of errors that you observe, both significant and non-significant. The denominator is all the doses observed being administered **plus** the doses ordered but not administered. The equation for calculating a medication error rate is as follows:

$$\text{Medication Error Rate} = \frac{\text{Number of errors observed}}{\text{Opportunities for errors}} \times 100$$

Where: Opportunities for errors equals the number of doses administered **plus** the number of doses ordered but not administered.

Comments

For example, you observed the administration of drugs to 20 patients. There were a total of 47 drugs administered (47 opportunities for errors). At the completion of the reconciliation of your Observations with the physicians' orders, you find that three medication errors were made in administration and one medication was omitted (ordered but not administered). The omitted dose is included in both the numerator and the denominator. Therefore, following the above formula, your equation would be as follows:

$$\frac{3 + 1}{47 + 1} \times 100 = 8.3\%$$

☆U.S. GPO 1989-0 [illegible]

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO. 0938-0400

DINING AREA & EATING ASSISTANCE WORKSHEET

PROVIDER NUMBER	SURVEY DATE

INSTRUCTIONS

TASKS 1. *Observe Dining Area*
2. *Note Meals Served/Review Physicians Orders*
3. *Note Assistance Provided*
4. *Note Deficiencies on Survey Summary Form*

⇒ * SAMPLE A MINIMUM OF FIVE (5) RESIDENTS ⇐

1. DINING AREA AND MEALS

a. Size does not restrict movement.

b. Accommodates all residents.

c. Cleanliness.

d. Adequate/comfortable lighting.

e. Adequate/comfortable ventilation.

2. SERVING OF MEALS *

a. Number of meals/time span between meal.

b. Conformance to physicians order.

c. Nutritional adequacy.

d. Adequacy of portions.

e. Residents eat approximately 75% of meals.

f. Puree dishes served individually.

g. Food cut, chopped or ground for individual resident needs.

h. Acceptable taste.

i. Proper temperature.

j. Plates covered.

FORM HCFA-523 (2-88)

SEE REVERSE

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO. 0938-0400

2. SERVING OF MEALS * *(continued)*

k. **Served promptly.**

l. **Residents ready for meal when served.**

m. **Attractive.**

n. **Utensils available.**

o. **Functional trays for bedfast residents.**

p. **Salt, pepper, sugar, other condiments on resident's trays unless contraindicated.**

q. **Medically able residents eating in dining area.**

r. **Bedtime nourishment offered.**

3. SUPERVISION OF RESIDENT NUTRITION

a. **Prompt assistance.**

b. **Proper assistance (spoon-feeding; supervision or instruction to develop eating skills).**

c. **Courteous and unhurried assistance.**

d. **Self-help devices present (straws, easy grip utensils, special cup, etc.).**

e. **Intake recorded/deviations** from normal are reported.

§ 488.110 Procedural guidelines.

SNF/ICF Survey Process. The purpose for implementing a new SNF/ICF survey process is to assess whether the quality of care, as intended by the law and regulations, and as needed by the resident, is actually being provided in nursing homes. Although the onsite review procedures have been changed, facilities must continue to meet all applicable Conditions/Standards, in order to participate in Medicare/Medicaid programs. That is, the methods used to compile information about compliance with law and regulations are changed; the law and regulations themselves are not changed. The new process differs from the traditional process, principally in terms of its emphasis on resident outcomes. In ascertaining whether residents grooming and personal hygiene needs are met, for example, surveyors will no longer routinely evaluate a facility's written policies and procedures. Instead, surveyors will observe residents in order to make that determination. In addition, surveyors will confirm, through interviews with residents and staff, that such needs are indeed met on a regular basis. In most reviews, then, surveyors will ascertain whether the facility is actually providing the required and needed care and services, rather than whether the facility is capable of providing the care and services.

The Outcome-Oriented Survey Process—Skilled Nursing Facilities (SNFs) and Intermediate Care Facilities (ICFs)

(a) General.
(b) The Survey Tasks.
(c) Task 1—Entrance Conference.
(d) Task 2—Resident Sample—Selection Methodology.
(e) Task 3—Tour of the Facility.
(f) Task 4—Observation/Interview/Medical Record Review (including drug regimen review).
(g) Task 5—Drug Pass Observation.
(h) Task 6—Dining Area and Eating Assistance Observation.
(i) Task 7—Forming the Deficiency Statement.
(j) Task 8—Exit Conference.
(k) Plan of Correction.
(l) Followup Surveys.
(m) Role of Surveyor.
(n) Confidentiality and Respect for Resident Privacy.
(o) Team Composition.
(p) Type of Facility-Application of SNF or ICF Regulations.
(q) Use of Part A and Part B of the Survey Report.

(a) *General.* A complete SNF/ICF facility survey consists of three components:

- Life Safety Code requirements;
- Administrative and structural requirements (Part A of the Survey Report, Form HCFA-525); and
- Direct resident care requirements (Part B of the Survey Report, Form HCFA-519), along with the related worksheets (HCFA 520 through 524).

Use this survey process for all surveys of SNFs and ICFs—whether freestanding, distinct parts, or dually certified. Do not use this process for surveys of Intermediate Care Facilities for Mentally Retarded (ICFs/MR), swing-bed hospitals or skilled nursing sections of hospitals that are not separately certified as SNF distinct parts. Do not announce SNF/ICF surveys ahead of time.

(b) *The Survey Tasks.* Listed below are the survey tasks for easy reference:

- Task 1. Entrance Conference.
- Task 2. Resident Sample—Selection Methodology.
- Task 3. Tour of the Facility. Resident Needs. Physical Environment. Meeting with Resident Council Representatives. Tour Summation and Focus of Remaining Survey Activity.
- Task 4. Observation/Interview/Medical Record. Review of Each Individual in the Resident Sample (including drug regimen review).
- Task 5. Drug Pass Observation.
- Task 6. Dining Area and Eating Assistance Observation.
- Task 7. Forming the Deficiency Statement (if necessary).
- Task 8. Exit Conference.

(c) *Task 1—Entrance Conference.* Perform these activities during the entrance conference in every certification and recertification survey:

- Introduce all members of the team to the facility staff, if possible, even though the whole team may not be present for the entire entrance conference. (All surveyors wear identification tags.)

- Explain the SNF/ICF survey process as resident centered in focus, and outline the basic steps.
- Ask the facility for a list showing names of residents by room number with each of the following care needs/treatments identified for each resident to whom they apply:

—Decubitus care
—Restraints
—Catheters
—Injections
—Parenteral fluids
—Rehabilitation service
—Colostomy/ileostomy care
—Respiratory care
—Tracheostomy care
—Suctioning
—Tube feeding

Use this list for selecting the resident sample.

- Ask the facility to complete page 2 of Form HCFA-519 (Resident Census) as soon as possible, so that the information can further orient you to the facility's population. In a survey of a SNF with a distinct part ICF, you may collect two sets of census data. However, consolidate the information when submitting it to the regional office. You may modify the Resident Census Form to include the numbers of licensed and certified beds, if necessary.
- Ask the facility to post signs on readily viewed areas (at least one on each floor) announcing that State surveyors are in the facility performing an "inspection," and are available to meet with residents in private. Also indicate the name and telephone number of the State agency. Handprinted signs with legible, large letters are acceptable.
- If the facility has a Resident Council, make mutually agreeable arrangements to meet privately with the president and officers and other individuals they might invite.
- Inform the facility that interviews with residents and Resident Councils are conducted privately, unless they independently request otherwise, in order to enhance the development of rapport as well as to allay any resident anxiety. Tell the facility that information is gathered from interviews, the tour, observations, discussions, record review, and facility officials. Point out that the facility will be given an opportunity to respond to all findings.

(d) *Task 2—Resident Sample—Selection Methodology.* This methodology is aimed at formulating a sample that reflects the actual distribution of care needs/treatments in the facility population.

Primarily performed on a random basis, it also ensures representation in the sample of certain care needs and treatments that are assessed during the survey.

(1) *Sample Size.* Calculate the size of the sample according to the following guide:

Number of residents in facility	Number of residents in sample[1]
0-60 residents	25% of residents (minimum—10).
61-120 residents.	20% of residents (minimum—15).
121-200 residents.	15% of residents (minimum—24).
201+ residents	10% of residents (minimum—30).

[1] Maximum—50.

Note that the calculation is based on the resident census, not beds. After determining the appropriate sample size, select residents for the sample in a random manner. You may, for example, select every fifth resident from the resident census, beginning at a random position on the list. For surveys of dually certified facilities or distinct part SNFs/ICFs, first use the combined SNF/ICF population to calculate the size of the sample, and then select a sample that reflects the proportions of SNF and ICF residents in the facility's overall population.

(2) *Special Care Needs/Treatments.* The survey form specifies several care needs/treatments that must always be reviewed when they apply to any facility residents. These include:

- Decubitus Care
- Restraints
- Catheters
- Injections, Parenteral Fluids, Colostomy/Ileostomy, Respiratory Care, Tracheostomy Care, Suctioning, Tube Feeding
- Rehabilitative Services (physical therapy, speech pathology and audiology services, occupational therapy)

Due to the relatively low prevalence of these care needs/treatments, appropriate residents may be either underrepresented or entirely omitted from the sample. Therefore, determine during the tour how many residents in the random selection fall into each of these care categories. Then, compare the number of such residents in the random selection with the total number of residents in the facility with each specified care need/treatment (based on either the resident census or other information provided by the facility).

Review no less than 25 percent of the residents in each of these special care needs/treatments categories. For example, if the facility has 10 residents with decubitus ulcers, but only one of these residents is selected randomly, review two more residents with decubitis ulcers (25% of 10 equals 2.5, so review a total of 3). Or, if the facility has two residents who require tube feeding, neither of whom is in the random selection, review the care of at least one of the these residents. This can be accomplished in the following manner:

Conduct in-depth reviews of the randomly selected residents and then perform limited reviews of additional residents as needed to cover the specified care categories. Such reviews are limited to the care and services related to the pertinent care areas only, e.g., catheters, restraints, or colostomy. Utilize those worksheets or portions of worksheets which are appropriate to the limited review. Refer to the Care Guidelines, as a resource document, when appropriate.

Always keep in mind that neither the random selection approach nor the review of residents within the specified care categories precludes investigation of other resident care situations that you believe might pose a serious threat to a resident's health or safety. Add to the sample, as appropriate.

(e) *Task 3—Tour of the Facility.* (1) *Purpose.* Conduct the tour in order to:

- Develop an overall picture of the types and patterns of care delivery present within the facility;
- View the physical environment; and
- Ascertain whether randomly selected residents are communicative and willing to be interviewed.

(2) *Protocol.* You may tour the entire facility as a team or separately, as long as all areas of the facility are examined by at least one team member. Success of the latter approach, however, is largely dependent on open intra-team communication and the ability of each team member to identify situations for further review by the team member of the appropriate discipline. You may conduct the tour with or without facility staff accompanying you, as you prefer. Facilities, however, vary in staff member availability. Record your notes on the Tour Notes Worksheet, Form HCFA-521.

Allow approximately three hours for the tour. Converse with residents, family members/significant others (if present), and staff, asking open-ended questions in order to confirm observations, obtain additional information, or corroborate information, (e.g., accidents, odors, apparent inappropriate dress, adequacy and appropriateness of activities). Converse sufficiently with residents selected for in-depth review to ascertain whether they are willing to be interviewed and are communicative. Observe staff interactions with other staff members as well as with residents for insight into matters such as resident rights and assignments of staff responsibilities.

Always knock and/or get permission before entering a room or interrupting privacy. If you wish to inspect a resident's skin, observe a treatment procedure, or observe a resident who is exposed, courteously ask permission from the resident if she/he comprehends, or ask permission from the staff nurse if the resident cannot communicate. Do not do "hands-on" monitoring such as removal of dressings; ask staff to remove a dressing or handle a resident.

(3) *Resident Needs.* While touring, focus on the residents' needs—physical, emotional, psychosocial, or spiritual—and whether those needs are being met. Refer to the following list as needed:

—Personal hygiene, grooming, and appropriate dress
—Position
—Assistive and other restorative devices
—Rehabilitation issues
—Functional limitations in ADL
—Functional limitations in gait, balance and coordination
—Hydration and nutritional status
—Resident rights
—Activity for time of day (appropriate or inappropriate)
—Emotional status
—Level of orientation
—Awareness of surroundings
—Behaviors
—Cleanliness of immediate environment (wheelchair, bed, bedside table, etc.)
—Odors
—Adequate clothing and care supplies as well as maintenance and cleanliness of same

(4) *Review of the Physical Environment.* As you tour each resident's room and auxiliary rooms, also examine them in connection with the physical environment requirements. You need not document physical environment on the Tour Notes Worksheet. Instead, you may note any negative findings directly on the Survey Report Form in the remarks section.

(5) *Meeting With Resident Council Representatives.* If a facility has a Resident Council, one or more surveyors meet with the respresentatives in a private area. Facility staff members do not attend unless specifically requested by the Council. Explain the purpose of the survey and briefly outline the steps in the survey process, i.e., entrance conference * * * exit conference. Indicate your interest in learning about the strengths of the facility in addition to any complaints or shortcomings. State that this meeting is one part of the information gathering; the findings have not yet been completed nor the conclusions formulated. Explain further, however, that the official survey findings are usually available within three months after the completion of the survey, and give the telephone number of the State agency office.

Use this meeting to ascertain strengths and/or problems, if any, from the consumer's perspective, as well as to develop additional information about aspects of care and services gleaned during the tour that were possibly substandard.

Conduct the meeting in a manner that allows for comments about any aspect of the facility. (See the section on Interview Procedures.) Use open-ended questions such as:

- "What is best about this home?"
- "What is worst?"
- "What would you like to change?"

In order to get more detail, use questions such as:

- "Can you be more specific?"
- "Can you give me an example?"
- "What can anyone else tell me about this?"

If you wish to obtain information about a topic not raised by the residents, use an approach like the following:

- "Tell me what you think about the food/staff/cleanliness here."
- "What would make it better?"
- "What don't you like? What do you like?"

(6) *Tour Summation and Focus of Remaining Survey Activity.* When the tour is completed, review the resident census data provided by the facility. Determine if the care categories specified in the section on Resident Sample are sufficiently represented in the random selection, make adjustments as needed, and complete the listing of residents on the worksheet labeled "Residents Selected for In-depth Review", Form HCFA-520.

Transcribe notes of a negative nature onto the SRF in the "Remarks" column under the appropriate rule. Findings from a later segment in the survey or gathered by another surveyor may combine to substantiate a deficiency. You need not check "met" or "not met" at this point in the survey. Discuss significant impressions/conclusions at the completion of each subsequent survey task, and transfer any negative findings onto the Survey Report Form in the Remarks section.

(f) *Task 4—Observation/Interview/Medical Record Review (including drug regimen review).* Perform the in depth review of each individual in the resident sample in order to ascertain whether the facility is meeting resident needs. Evaluate specific indicators for each resident, utilizing the front and back of the "Observation/Interview/Record Review (OIRR)" worksheet, Form HCFA-524. You may prefer to perform the record review first, complete resident/staff/family observations and interviews, and finally, return to the record for any final unresolved issues. On the other hand, you may prefer to do the interviews first. Either method is acceptable. Whenever possible, however, complete one resident's observation/interview/medical record review and document the OIRR before moving onto another resident. If because of the facility layout, it is more efficient to do more than one record review at a time, limit such record review to two or three residents so your familiarity with the particular resident and continuity of the OIRR are not compromised.

(1) *Observation.* Conduct observations concurrently with interviews of residents, family/significant others, and discussions with direct care staff [of the various disciplines involved. In multi-facility operations, whenever possible, observe staff that is regularly assigned to the facility in order to gain an understanding of the care and services usually provided.] Maintain respect for resident privacy. Minimize disruption of the operations of the facility or impositions upon any resident as much as possible. Based upon your observations of the residents' needs, gather information about any of the following areas, as appropriate:

Bowel and bladder training
Catheter care
Restraints
Injections
Parenteral fluids
Tube feeding/gastrostomy
Colostomy/ileostomy
Respiratory therapy
Tracheostomy care
Suctioning

(2) *Interviews.* Interview each resident in private unless he/she independently requests that a facility staff member or other individual be present. Conduct the in-depth interview in a nonthreatening and noninvasive fashion so as to decrease anxiety and defensiveness. The open-ended approach described in the section on the Resident Council is also appropriate for the in-depth interview. While prolonged time expenditure is not usually a worthwhile use of resources or the resident's time, do allow time initially to establish rapport.

At each interview:

- Introduce yourself.
- Address the resident by name.
- Explain in simple terms the reason for your visit (e.g., to assure that the care and services are adequate and appropriate for each resident).
- Briefly outline the process—entrance conference, tour, interviews, observations, review of medical records, resident interviews, and exit conference.
- Mention that the selection of a particular resident for an interview is not meant to imply that his/her care is substandard or that the facility provides substandard care. Also mention that most of those interviewed are selected randomly.
- Assure that you will strive for anonymity for the resident and that the interview is used in addition to medical records, observations, discussions, etc., to capture an accurate picture of the treatment and care provided by the facility. Explain that the official findings of the survey are usually available to the public about three months after completion of the survey, but resident names are not given to the public.
- When residents experience difficulty expressing themselves:
  - —Avoid pressuring residents to verbalize
  - —Accept and respond to all communication
  - —Ignore mistakes in word choice
  - —Allow time for recollection of words
  - —Encourage self-expression through any means available
- When interviewing residents with decreased receptive capacity:
  - —Speak slowly and distinctly
  - —Speak at conversational voice level
  - —Sit within the resident's line of vision
- Listen to all resident information/allegations without judgment. Infor-

mation gathered subsequently may substantiate or repudiate an allegation.

The length of the interview varies, depending on the condition and wishes of the resident and the amount of information supplied. Expect the average interview, however, to last approximately 15 minutes. Courteously terminate an interview whenever the resident is unable or unwilling to continue, or is too confused or disoriented to continue. Do, however, perform the other activities of this task (observation and record review). If, in spite of your conversing during the tour, you find that less than 40 percent of the residents in your sample are sufficiently alert and willing to be interviewed, try to select replacements so that a complete OIRR is performed for a group this size, if possible. There may be situations, however, where the resident population has a high percentage of confused individuals and this percentage is not achievable. Expect that the information from confused individuals can be, but is not necessarily, less reliable than that from more alert individuals.

Include the following areas in the interview of each resident in the sample:

Activities of daily living
Grooming/hygiene
Nutrition/dietary
Restorative/rehabilitation care and services
Activities
Social services
Resident rights

Refer to the Care Guidelines "evaluation factors" as a resource for possible elements to consider when focusing on particular aspects of care and resident needs.

Document information obtained from the interviews/observations on the OIRR Worksheet. Record in the "Notes" section any additional information you may need in connection with substandard care or services. Unless the resident specifically requests that he/she be identified, do not reveal the source of the information gleaned from the interview.

(3) *Medical Record Review.* The medical record review is a three-part process, which involves first reconciling the observation/interview findings with the record, then reconciling the record against itself, and lastly performing the drug regimen review.

Document your findings on the OIRR Worksheet, as appropriate, and summarize on the Survey Report Form the findings that are indicative of problematic or substandard care. Be alert for repeated similar instances of substandard care developing as the number of completed OIRR Worksheets increases.

NOTE: The problems related to a particular standard or condition could range from identical (e.g., meals not in accordance with dietary plan) to different but related (e.g., nursing services—lapse in care provided to residents with catheters, to residents with contractures, to residents needing assistance for personal hygiene and residents with improperly applied restraints).

(i) *Reconciling the observation/interview findings with the record.* Determine if:

- An assessment has been performed.
- A plan with goals has been developed.
- The interventions have been carried out.
- The resident has been evaluated to determine the effectiveness of the interventions.

For example, if a resident has developed a decubitus ulcer while in the facility, record review can validate staff and resident interviews regarding the facility's attempts at prevention. Use your own judgment; review as much of the record(s) as necessary to evaluate the care planning. Note that facilities need not establish specific areas in the record stating "Assessment," "Plan," "Intervention," or "Evaluation" in order for the documentation to be considered adequate.

(ii) *Reconciling the record with itself.* Determine:

- If the resident has been properly assessed for all his/her needs.
- That normal and routine nursing practices such as periodic weights, temperatures, blood pressures, etc., are performed as required by the resident's conditions.

(iii) *Performing the drug regimen review.* The purpose of the drug regimen review is to determine if the pharmacist has reviewed the drug regimen on a monthly basis. Follow the procedures in Part One of Appendix N, Surveyor Procedures for Pharmaceutical Service Requirements in Long-Term Care Facilities. Fill in the appropriate boxes on the top left hand corner of the reverse side of the OIRR Worksheet, Form HCFA-524. Appendix N lists many irregularities that can occur. Review at least six different indicators on each survey. However, the same six indicators need not be reviewed on every survey.

NOTE: If you detect irregularities and the documentation demonstrates that the pharmacist has notified the attending physician, do not cite a deficiency. Do, however, bring the irregularity to the attention of the medical director or other facility official, and note the official's name and date of notification on the Survey Report Form.

(g) *Task 5—Drug Pass Observation.* The purpose of the drug pass observation is to observe the actual preparation and administration of medications to residents. With this approach, there is no doubt that the errors detected, if any, are errors in drug administration, not documentation. Follow the procedure in Part Two of Appendix N, Surveyor Procedures for Pharmaceutical Service Requirements in Long-Term Care Facilities, and complete the Drug Pass Worksheet, Form HCFA-522. Be as neutral and unobtrusive as possible during the drug pass observation. Whenever possible, select one surveyor, who is a Registered Nurse or a pharmacist, to observe the drug pass of approximately 20 residents. In facilities where fewer than 20 residents are receiving medications, review as many residents receiving medications as possible. Residents selected for the in-depth review need not be included in the group chosen for the drug pass; however, their whole or partial inclusion is acceptable. In order to get a balanced view of a facility's practices, observe more than one person administering a drug pass, if feasible. This might involve observing the morning pass one day in Wing A, for example, and the morning pass the next day in Wing B.

Transfer findings noted on the "Drug Pass" worksheet to the SRF under the appropriate rule. If your team concludes that the facility's medication error rate is 5 percent or more, cite the deficiency under Nursing Services/Administration of Drugs. Report the error rate under F209. If the deficiency is at the standard level, cite it in Nursing Services, rather than Pharmacy.

(h) *Task 6—Dining Area and Eating Assistance Observation.* The purpose of this task is to ascertain the extent to which the facility meets dietary needs, particularly for those who require eating assistance. This task also yields information about staff interaction with residents, promptness and appropriateness of assistance, adaptive equipment usage and availability, as well as appropriateness of dress and hygiene for meals.

For this task, use the worksheet entitled "Dining Area and Eating Assistance Observation" (Form HCFA-523). Observe two meals; for a balanced view, try to observe meals at different times of the day. For example, try to observe a breakfast and a dinner rather than two breakfasts. Give particular care to performing observations as unobtrusively as possible. Chatting with residents and sitting down nearby may help alleviate resident anxiety over the observation process.

Select a minimum of five residents for each meal observation and include residents who have their meals in their rooms. Residents selected for the in-depth review need not be included in the dining and eating assistance observation; however, their whole or partial inclusion is acceptable. Ascertain the extent to which the facility assesses, plans, and evaluates the nutritional care of residents and eating assistance needs by reviewing the sample of 10 or more residents. If you are unable to determine whether the facility meets the standards from the sample reviewed, expand the sample and focus on the specific area(s) in question, until you can formulate a conclusion about the extent of compliance. As with the other survey tasks, transfer the findings noted on the "Dining &

Eating Assistance Observation" worksheet to the Survey Report Form.

(i) *Task 7—Forming the Deficiency Statement.* (1) *General.* The Survey Report Form contains information about all of the negative findings of the survey. Be sure to transfer to the Survey Report Form data from the tour, drug pass observation, dining area and eating assistance observation, as well as in-depth review of the sample of residents. Transfer only those findings which could possibly contribute to a determination that the facility is deficient in a certain area.

Meet as a group in a pre-exit conference to discuss the findings and make conclusions about the deficiencies, subject to information provided by facility officials that may further explain the situation. Review the summaries/conclusions from each task and decide whether any further information and/or documentation is necessary to substantiate a deficiency. As the facility for additional information for clarification about particular findings, if necessary. Always consider information provided by the facility. If the facility considers as acceptable, practices which you believe are not acceptable, ask the facility to backup its contention with suitable reference material or sources and submit them for your consideration.

(2) *Analysis.* Analyze the findings on the Survey Report Form for the degree of severity, frequency of occurrence and impact on delivery of care or quality of life. The threshold at which the frequency of occurrences amounts to a deficiency varies from situation to situation. One occurrence directly related to a life-threatening or fatal outcome can be cited as a deficiency. On the other hand, a few sporadic occurrences may have so slight an impact on delivery of care or quality of life that they do not warrant a deficiency citation. Review carefully all the information gathered. What may appear during observation as a pattern, may or may not be corroborated by records, staff, and residents. For example, six of the 32 residents in the sample are dressed in mismatched, poorly buttoned clothes. A few of the six are wearing slippers without socks. A few others are wearing worn clothes. Six occurrences might well be indicative of a pattern of susbstandard care. Close scrutiny of records, discussions with staff, and interviews reveal, however, that the six residents are participating in dressing retraining programs. Those residents who are without socks, chose to do so. The worn clothing items were also chosen—they are favorites.

Combinations of substandard care such as poor grooming of a number of residents, lack of ambulation of a number of residents, lack of attention to positioning, poor skin care, etc., can yield a deficiency in nursing services just as 10 out of 10 residents receiving substandard care for decubiti yields a deficiency.

(3) *Deficiencies Alleged by Staff or Residents.* If staff or residents allege deficiencies, but records, interviews, and observation fail to confirm the situation, it is unlikely that a deficiency exists. Care and services that are indeed confirmed by the survey to be in compliance with the regulatory requirements, but considered deficient by residents or staff, cannot be cited as deficient for certification purposes. On the other hand, if an allegation is of a very serious nature (e.g., resident abuse) and the tools of record review and observation are not effective because the problem is concealed, obtain as much information as possible or necessary to ascertain compliance, and cite accordingly. Residents, family, or former employees may be helpful for information gathering.

(4) *Composing the Deficiency Statement.* Write the deficiency statement in terms specific enough to allow a reasonably knowledgeable person to understand the aspect(s) of the requirement(s) that is (are) not met. Do not delve into the facility's policies and procedures to determine or speculate on the root cause of a deficiency, or sift through various alternatives in an effort to prescribe an acceptable remedy. Indicate the data prefix tag and regulatory citation, followed by a summary of the deficiency and supporting findings using resident identifiers, not resident names, as in the following example.

F102 SNF 405.1123(b).—Each resident has not had a physician's visit at least once every 30 days for the first 90 days after admission. Resident #1602 has not been seen by a physician since she was admitted 50 days ago. Her condition has deteriorated since that time (formulation of decubiti, infections).

When the data prefix tag does not repeat the regulations, also include a short phrase that describes the prefix tag (e.g., F117 decubitus ulcer care). List the data tags in numerical order, whenever possible.

(j) *Task 8—Exit Conference.* The purpose of the exit conference is to inform the facility of survey findings and to arrange for a plan of correction, if needed. Keep the tone of the exit conference consistent with the character of the survey process—inspection and enforcement. Tactful, business-like, professional presentation of the findings is of paramount importance. Recognize that the facility may wish to respond to various findings. Although deficiency statements continue to depend, in part, on surveyor professional judgment, support your conclusions with resident-specific examples (identifiers other than names) whenever you can do so without compromising confidentiality. Before formally citing deficiencies, discuss any allegations or findings that could not be substantiated during earlier tasks in the process. For example, if information is gathered that suggests a newly hired R.N. is not currently licensed, ask the facility officials to present current licensure information for the nurse in question. Identify residents when the substandard care is readily observed or discerned through record review. Ensure that the facility improves the care provided to all affected residents, not only the identified residents. Make clear to the facility that during a follow-up visit the surveyors may review residents other than those with significant problems from the original sample, in order to see that the facility has corrected the problems overall. Do not disclose the source of information provided during interviews, unless the resident has specifically requested you to inform the facility of his/her comments or complaints. In accordance with your Agency's policy, present the Statement of Deficiencies, form HCFA-2567, on site or after supervisory review, no later than 10 calendar days following the survey.

(k) *Plan of Correction.* Explain to the facility that your role is to identify care and services which are not consistent with the regulatory requirements, rather than to ascertain the root causes of deficiencies. Each facility is expected to review its own care delivery. Subsequent to the exit conference, each facility is required to submit a plan of correction that identifies necessary changes in operation that will assure correction of the cited deficiencies. In reviewing and accepting a proposed plan of correction, apply these criteria.

- Does the facility have a reasonable approach for correcting the deficiencies?
- Is there a high probability that the planned action will result in compliance?
- Is compliance expected timely?

Plans of correction specific to residents identified on the deficiency statement are acceptable only where the deficiency is determined to be unique to that resident and not indicative of a possible systemic problem. For example, as a result of an aide being absent, two residents are not ambulated three times that day as called for in their care plans. A plan of correction that says "Ambulate John Jones and Mary Smith three times per day," is not acceptable. An acceptable plan of correction would explain changes made to the facility's staffing and scheduling in order to gurantee that staff is available to provide all necessary services for all residents.

Acceptance of the plan of correction does not absolve the facility of the responsibility for compliance should the implementation not result in correction and compliance. Acceptance indicates the State agency's acknowledgement that the facility indicated a willingness and ability to make corrections adequately and timely.

Allow the facility up to 10 days to prepare and submit the plan of correction to the State agency, however, follow your SA policy if the timeframe is shorter. Retain the various survey worksheets as well as the Survey Report Form at the State agency. Forward the deficiency statement to the HCFA regional office.

(l) *Follow-up Surveys.* The purpose of the follow-up survey is to re-evaluate the specific types of care or care delivery patterns that were cited as deficient during the original survey. Ascertain the corrective status of all deficiencies cited on the HCFA-2567. Because this survey process focuses on the actual provision of care and services, revisits are almost always necessary to ascertain whether the deficiencies have indeed been corrected. The nature of the deficiencies dictates the scope of the follow-up visit. Use as many tasks or portions of the Survey Report Form(s) as needed to ascertain compliance status. For example, you need not perform another drug pass if no drug related deficiencies were cited on the initial survey. Similarly, you need not repeat the dining area and eating assistance observations if no related problems were identified. All or some of the aspects of the observation/interview/medical record review, however, are likely to be appropriate for the follow-up survey.

When selecting the resident sample for the follow-up, determine the sample size using the same formula as used earlier in the survey, with the following exceptions:

- The maximum sample size is 30 residents, rather than 50.
- The minimum sample size of 10 residents does not apply if only one care category was cited as deficient and the total number of residents in the facility in that category was less than 10 (e.g., deficiency cited under catheter care and only five residents have catheters).

Include in the sample those residents who, in your judgment, are appropriate for reviewing vis-a-vis the cited substandard care. If possible, include some residents identified as receiving substandard care during the initial survey. If after completing the follow-up activities you determine that the cited deficiencies were not corrected, initiate adverse action procedures, as appropriate.

(m) *Role of Surveyor.* The survey and certification process is intended to determine whether providers and suppliers meet program participation requirements. The primary role of the surveyor, then, is to assess the quality of care and services and to relate those findings to statutory and regulatory requirements for program participation.

When you find substandard care or services in the course of a survey, carefully document your findings. Explain the deficiency in sufficient detail so that the facility officials understand your rationale. If the cause of the deficiency is obvious, share the information with the provider. For example, if you cite a deficiency for restraints (F118), indicate that restraints were applied backwards on residents 1621, 1634, 1646, etc.

In those instances where the cause is not obvious, do not delve into the facility's policies and procedures to determine the root cause of any deficiency. Do not recommend or prescribe an acceptable remedy. The provider is responsible for deciding on and implementing the action(s) necessary for achieving compliance. For the restraint situation in the example above, you would not ascertain whether the improper application was due to improper training or lack of training, nor would you attempt to identify the staff member who applied the restraints. It is the provider's responsibility to make the necessary changes or corrections to ensure that the restriants are applied properly.

A secondary role for the surveyor is to provide general consultation to the provider/consumer community. This includes meeting with provider/consumer associations and other groups as well as participating in seminars. It also includes informational activities, whereby you respond to oral or written inquiries about required outcomes in care and services.

(n) *Confidentiality and Respect for Resident Privacy.* Conduct the survey in a manner that allows for the greatest degree of confidentiality for residents, particularly regarding the information gathered during the in-depth interviews. When recording observations about care and resident conditions, protect the privacy of all residents. Use a code such as resident identifier number rather than names on worksheets whenever possible. Never use a resident's name on the Deficiency Statement, Form HCFA-2567. Block out resident names, if any, from any document that is disclosed to the facility, individual or organization.

When communicating to the facility about substandard care, fully identify the resident(s) by name if the situation was identified through observation or record review. Improperly applied restraints, expired medication, cold food, gloves not worn for a sterile procedure, and diet inconsistent with order, are examples of problems which can be identified to the facility by resident name. Information about injuries due to broken equipment, prolonged use of restraints, and opened mail is less likely to be obtained through observation or record review. Do not reveal the source of information unless actually observed, discovered in the record review, or requested by the resident or family.

(o) *Team Composition.* Whenever possible, use the following survey team model:

SNF/ICF SURVEY TEAM MODEL

In facilities with 200 beds or less, the team size may range from 2 to 4 members. If the team size is:

• *2 members:* The team has at least one RN plus another RN or a dietitian or a pharmacist.

• *3-4 member:* In addition to the composition described above, the team has one or two members of any discipline such as a social worker, sanitarian, etc.

If the facility has over 200 beds *and* the survey will last more than 2 days, the team size may be greater than 4 members. Select additional disciplines as appropriate to the facility's compliance history.

Average onsite time per survey: 60 person hours (Number of surveyors multiplied by the number of hours on site)

Preferably, team members have gerontological training and experience. Any member may serve as the team leader, consistent with State agency procedures. In followup surveys, select disciplines based on major areas of correction. Include a social worker, for example, if the survey revealed major psychosocial problems. This model does not consider integrated survey and Inspection of Care review teams, which typically would be larger

(p) *Type of Facility—Application of SNF or ICF Regulations.* Apply the regulations to the various types of facilities in the following manner:

● Freestanding Skilled Nursing Facility (SNF)	Apply SNF regulations.
● Freestanding Intermediate Care Facility (ICF)	Apply ICF regulations.
● SNF Distinct Part of a Hospital	Apply SNF regulations.
● ICF Distinct Part of a Hospital	Apply ICF regulations.
● Dually Certified SNF/ICF	Apply SNF regulations and 442.346(b).
● Freestanding SNF with ICF Distinct Part (Regardless of the proportion of SNF and ICF beds, the facility type is determined by the higher level of care. Therefore, LTC facilities with distinct parts are defined as SNFs with ICF distinct parts.)	Apply SNF regulations for SNF unit. Apply ICF regulations for ICF distinct part. Apply both SNF and ICF regulations for shared services (e.g., dietary). If the same deficiency occurs in both the SNF and ICF components of the facility, cite both SNF and ICF regulations. If the deficiency occurs in the SNF part only, cite only the SNF regulation. If the deficiency occurs in the ICF part only, cite only the ICF regulation.

(q) *Use of Part A and Part B of the Survey Report.* (1) *Use of Part A (HCFA-525).*—Use Part A for initial certification surveys only, except under the following circumstances:

• When a terminated facility requests program participation 60 days or more after termination. Treat this situation as a request for initial certification and complete Part A of the survey report in addition to Part B.

• If an ICF with a favorable compliance history requests to covert a number of beds to SNF level, complete both Part A and Part B for compliance with the SNF requirements. If distinct part status is at issue, also examine whether it meets the criteria for certification as a distinct part.

(i) *Addendum for Outpatient Physical Therapy (OPT) or Speech Pathology Services.* Use the Outpatient Physical Therapy—Speech Pathology SRF

(HCFA-1893) as an addendum to Part A.

(ii) *Resurvey of Participating Facilities.* Do not use Part A for resurveys of participating SNFs and ICFs. A determination of compliance, based on documented examination of the written policies and procedures and other pertinent documents during the initial survey, establishes the facility's compliance status with Part A requirements. This does not preclude citing deficiencies if they pertain to administrative or structural requirements from Part A that are uncovered incidental to a Part B survey. As an assurance measure, however, each facility at the time of recertification must complete an affidavit (on the HCFA-1516) attesting that no substantive changes have occurred that would affect compliance. Each facility must also agree to notify the State agency immediately of any upcoming changes in its organization or management which may affect its compliance status. If a new administrator is unable to complete the affidavit, proceed with the survey using the Part B form and worksheets; do not use the Part A form. The survey cannot be considered complete, however, until the affidavit is signed. If the facility fails to complete the affidavit, it cannot participate in the program.

(iii) *Substantial Changes in a Facility's Organization and Management.* If you receive such information, review the changes to ensure compliance with the regulations. Request copies of the appropriate documents (e.g., written policies and procedures, personnel qualifications, or agreements) if they were not submitted. If the changes have made continued compliance seem doubtful, determine through a Part B survey whether deficiencies have resulted. Cite any deficiencies on the HCFA-2567 and follow the usual procedures.

(2) *Use of Part B (HCFA-519).* Use Part B and the worksheets for all types of SNF and ICF surveys—initials, recertifications, followup, complaints, etc.

The worksheets are:

- HCFA-520—Residents Selected for Indepth Review
- HCFA-521—Tour Notes Worksheet
- HCFA-522—Drug Pass Worksheet
- HCFA-523—Dining Area and Eating Assistance Worksheet
- HCFA-5245—Observation/Interview/Record Review Worksheet

For complaint investigations, perform a full or partial Part B survey based on the extent of the allegations. If the complaint alleges substandard care in a general fashion or in a variety of services and care areas, perform several tasks or a full Part B survey, as needed. If the complaint is of a more specific nature, such as an allegation of improper medications, perform an appropriate partial Part B survey, such as a drug pass review and a review of selected medical records.

§ 488.115 Care guidelines.

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Resident Rights					
F53 SNF 405.1121(k)(1) ICF 442.311(a)		Ask Resident: - Did you receive a copy of the Resident's Bill of Rights? Was it explained to you?	Looked for signed acknowledgement of receipt of resident rights information. Residents unable to sign name may have their "mark" witnessed. Look for written statement of charges services. Social Work records may idicate patient rights information discussed with resident.	Because of the confusion surrounding admission to a new facility and the large amount of information given to a resident or resident's family on admission, information given at this time is often forgotten. Therefore, surveyor should verify resident's recollection with staff interviews and record checks. Written information on services and costs must be given to the resident, as well as copies of residents rights and responsibilities. Copies of residents' rights should also be available to patients and visitors, e.g., in resident lounges, lobbies, or other area where residents and visitors could easily see and read them.	Notification of Change in Status 405.1121(j) 442.307 Patient Care Policies 405.1121(e) 442.308 442.309 442.310 442.305 Medical Direction 405.1122(a) Medical Records 405.1132(b)(d) 442.310
F54 SNF 405.1121(h)(1) ICF 442.311(a)(1)					
A. Information*					
F55 SNF 405.1121(h)(1) ICF 442.311(a)(2) 1. Rights and Responsibilities	Where is information concerning resident rights and responsibilities available in the facility?	- Were you told of any responsibilities you have in living here?			
F56 SNF 405.1121(k)(1) ICF 442.311(a)(3) 2. Rules of Resident Conduct		- Were you given a chance to ask questions?			
F57 SNF 405.1121(h)(2) ICF 442.311(a)(4) 3. Resident Acknowledgement		- Did he/she receive a written copy of services provided by the facility and any additional costs for these services?			

INTENT
To assure that the resident maintains,
in so far as possible, those personal rights
that are a part of normal, adult life,
and including the right to personal dignity.

*Information concerning incompetent residents is given in L. Delegation of Rights and Responsibilities.

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F58 SNF 405.1121(k)(2) ICF 442.311(a)(4) 4. Resident informed in writing of changes in services and charges for services.		Ask Resident: - If there are changes in services or costs does someone explain these? Ask Administrative Staff: - How do residents learn what is expected of them? - How do they learn about any changes in the facility's procedures and/or costs?			
F59 SNF 405.1121(k)(2) ICF 442.311(a)(4) 5. Information to resident of services not covered by Medicare or Medicaid and not covered in the basic rate.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
B. Medical Condition & Treatment F60-64 SNF 405.1121(k)(2) ICF 442.311(b)		Ask Resident: - Has your doctor discussed your health with you, how is it, what's wrong, and what you can expect in the future? - Have you had the opportunity to help plan what you need and how you are taken care of? - Do you know that you can refuse treatment or medication? - Have you ever refused medication or treatment? - What happened when you did? Ask Staff: - Is the facility participating in any experimental research? If yes, ask what residents are involved. Interview a sample of these residents. Ask Resident (or Guardian: - Are you participating in the _______ study? - Was this explained to you well enough so that you understand what the study is about and any risks that may be involved?	If the resident has not been informed of his/her medical condition, physician notes should document that the resident was not informed because it was medically contraindicated. Do care plans or other documentation reflect resident participation in care planning? If resident states he/she has refused treatment or medication does documentation indicate adherence to/violation of resident rights. Review records of residents identified as participating in a clinical research study. Are informed consent forms signed? Do these signed forms list all known risks for the resident? All needed informed consent statements are present and properly signed.	Unless there is documentation that the residents medical condition should not be discussed with him/her resident interviews/record reviews should indicate that the resident and physician have discussed his/her medical condition." If you cannot confirm that this has occurred, interview staff to get further clarification. Almost all residents who are able to participate to some extent in their care planning do so. You should find evidence of this for the majority of the residents (e.g., care planning interview, nurses notes, social worker progress notes). Residents do have the right to refuse medication or other treatment, but you would expect that the facility would discuss the implications of this refusal with the resident and possibly do some "gentle persuasion"."	Patient Care Management 405.1124(d) 442.319 442.341

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F60–64 (cont'd)				However, except in an emergency situation force should never be used to compel a resident to accept medication or treatment. Deceit is also a violation of resident rights, except in the case of therapeutically indicated placebos ordered by the physician. Any resident participating in research studies should fully understand the implication of the study. The facility is not in compliance with the resident rights regulation if the resident consents to participate in a clinical study without full knowledge of the study. (Record review only as other nonclinical studies may not require informed consent).	

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
C. Transfer and Discharge F65–68 SNF 405.1121(k)(4) ICF 442.311(c)	Look for residents that may be inappropriately placed physically – an alert resident rooming with a confused, noisy resident; very ill resident placed far from the nurses station; residents not compatible with each other, (e.g., different life-styles, habits, etc.).	Ask Resident: - How well do you get along with your roommate? - Have you ever been moved from one room to another? If yes, why? - How were you involved in the decision to move? - How much time was there between the time they told you you were to be moved, and when you were moved? - Have you asked for your room to be changed? Ask Direct Care and Other Staff: - What are some of the reasons residents rooms are changed? - What are some of the reasons for discharge of residents or transfer to a hospital or LTC facility? - How are residents involved in the decision to move? - If a resident requests a room change, how is this handled? - When a resident requests a room change are the following areas of consideration presented and discussed:	Nursing, physician, and/or social service progress notes should indicate reason for transfer and discussion with resident and/or family/guardian. If staff interviews give you cause to feel that transfers and discharges may be in violation of these regulations, review a sample of closed records for transfer information on how it was handled. If residents are transferred between facilities with common ownership and similar levels of care, transfers must be reviewed to determine reasons for transfer. Efforts to maintain the census is not an acceptable reason for transfer. Do discharge records review: - reason for discharge, medical non-payment or need for different level of care?	To be in compliance with transfer and discharge regulations the facility must be able to confirm that all discharges/transfers were for medical or resident welfare reasons, or non-payment. Welfare reasons include physical, emotional, social issues. Transfers and discharges made solely for the convenience of the facility are unacceptable. (Relocation to accommodate contagious or other disorders requiring isolation procedures are not for the convenience of the facility).	Status Change Notification 405.1121(j) Medical Records 405.1132(c)(e) 442.318(c)(4) Transfer Agreement 405.1133(a)(2) 442.307(b)(1)(2)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F65-68 (cont'd)		+ cost factors + resident welfare + resident's reason for requesting the move + facility's assessment of whether the move would be beneficial or not for the resident.			

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
D. Exercising Rights F69 SNF 405.1121(k)(5) ICF 442.311(d)	Do residents appear comfortable when speaking to the surveyors as opposed to being afraid that someone may see them or overhear their conversation?	Ask Resident: - Do you belong to, or have representation on the resident council? - Are you informed of changes in the facility that will affect you? - Are you given a chance to express views on these changes prior to their implementation? - Does the facility assist in arranging for you to vote either at the polls or via absentee ballot? - Are you assisted in obtaining legal or Social Services if needed? - Do you feel comfortable in expressing yourself freely or are you concerned about retaliation? - Is staff/administration responsive to complaints? Do you know who to complain to? Ask Staff: - What arrangements are made for residents to vote? - How do you handle it if someone needs a lawyer or other service that you don't provide?	Review resident council documentation, as available, to determine level of activity. Review social work or progress notes for legal referrals. Is there documentation in progress notes or elsewhere, of resident complaints and disposition of complaints?	Compliance determinations will be made based primarily on resident/staff interviews and the correlation of interview information with documentation in the Medical record. If residents ask, they should be allowed to speak to the surveyor without facility personnel being present. However the resident has the right to have a third party of their choosing present during an interview.	Social Services 405.1130 442.344

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LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
E. Financial Affairs F72-78 SNF 405.1121(k)(6) 405.1121(m) ICF 442.311(e) 442.320		Ask Residents: - Are you able to take care of your own financial affairs? - Does the facility keep some money for you that you can have when you request it? - When you ask for this money, how quickly do you get it? - Do you know the amount of money you have available at this time?			Social Services 405.1130(a)
		- If the facility pays bills for you do they periodically provide an itemized listing of the transactions they have made? - When did you receive the last itemized statement? - Are you comfortable that your funds are taken care of correctly? - If you deposit money or valuables with the facility, do you receive a receipt for this deposit? - Are you or your family able to review your financial records when you request to do so? - Have you ever had money or anything else stolen? If so, what was done about it?	A copy of the statement should be in the residents financial record and given to the resident at least quarterly. Receipts, account logs showing deposits/withdrawals, authorization/reasons for withdrawals, and interest earned should be reviewed. If resident indicates there may be a problem, an in-depth interview should be conducted. Resident records indicate separate financial records from facility records.	Residents should have reasonable access to their funds (may not be available at 2 A.M.) and should have at least a quarterly accounting of their funds. If questions arise they should be resolved. Personal possessions and funds received from the residents should be protected from theft and other loss. If losses do occur there should be: 1. a procedure which is implemented to investigate the loss, and 2. a plan to prevent recurrence. Resident funds must not be appropriated for facility furnishings, linen direct care supplies, etc	

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F72-78 (cont'd)		- Does the home provide safe-keeping for valuables? - Have they ever lost anything of yours? Ask Staff: - What is the procedure when residents lose personal belongings? Valuables? - How are resident personal funds handled? - What is your procedure when a resident asks to get an accounting of their funds? * The special needs of residents with Alzheimer's disease who "lose" personal possessions should be noted. Individuals in stages 2 and 3 of Alzheimer's disease sometimes believe their personal possessions were stolen.			

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F. Freedom From Abuse and Restraints F79-83 SNF 405.1121(k)(7) ICF 442.311(*i*)	- How many residents are physically restrained? - What type or restraints are used? - Are they applied correctly? - What is the apparent physical/mental condition of those residents restrained? - Do you observe the release of restraints every 2 hours and the provision of at least 10 minutes exercise for the resident? - Do staff respond to request for water, assistance to bathroom, etc., from a resident who is restrained? What is the interval between request and response?	Ask Resident: - Why are you wearing this? - How often is this worn? - Do you know what would happen if it were removed? - How often is it removed? - What is done for you when the restraint is removed? - For nonrestrained resident-- + Have you ever been restrained? + For what reason? + What explanation was given for the restraint? - Do you ever feel that you receive medication when you don't need it?	Look for a physician's order for the restraint. Review nurses', physicians' progress notes re: reason for restraints and resident reaction to them. Also any alternative methods tried. What time of day are restraints most often applied? Review schedule of releasing restraints. Care plans: - When restraint is to be used. - For how long. - What are plans for alternative measures. - Is the resident periodically re-evaluated? If appropriate are the Social Service or activities departments involved in providing different directions for resident attention?	There must be a physician's order for all restraints, including "safety devices" which are defined in some State laws. Progress notes should show evidence that methods other than restraints were initially used to protect the resident from injury, and that restraints were used only when other methods were not adequate If used in an "emergency" the reason for use must be documented and show that: a. Its use was necessary to protect the resident from injury. b. Its use was necessary to protect others from injury. The resident must be observed by a staff member at least every 30 mins. while restrained. The restraints must be released and the resident exercised, toileted, etc. at least every 2 hours.	Nursing Services 405.1124(c)(5) Rehab Nursing 405.1124(e) Patient Care Management 405.1124(d)

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F79–83 (cont'd)	- How often are restrained residents observed by staff? - Observe effect on residents. Do you see what may be signs of over-medication? - How often is this observed? - Residents should be free from mental and physical abuse. -Observe interaction of staff and residents for any sign of harassment, humiliation or threats. - Do residents appear comfortable with staff? - Look for numbers of residents with bruises or other injuries (skin of the elderly bruises easily, so do not automatically assume abuse or injury). - Observe resident to resident interactions and staff response to any physical or mental abuse of one resident to another.	Ask Staff: - What is the facility policy regarding re: restraints? - What is considered an "emergency" need for restraints? - What is the most common reason for use of restraints? - Do you try any alternative measures before using restraints? - What information do you give the physician to help him make the decision to order restraints? - What do you routinely do for the resident when you periodically release the restraints? - Does use of restraints increase on evenings or nights when there are fewer staff members? - Have you had any accidents or incidents in the last year while residents were restrained? - How do you define the difference between a "safety device" and a "restraint"? - How do your policies differ in regard to "safety devices" and restraints?	Who authorizes the use of restraints in an emergency? Do progress notes indicate that a professional staff member authorized the use of "emergency" restraints? There should be documentation that the use of "emergency" restraint has been promptly reported to the residents physician. Review incident and accident reports to identify any problematic trends. Does the drug regimen review indicate appropriate use of psychoactive drugs? Are there resident complaints documented? What is the resolution of these complaints?	The restraint must be applied correctly. If the use of restraints increased during evening and night hours review progress notes, nurses notes and staffing to make a determination as to whether the restraints are justified or if they are for staff convenience. Care plans should plan not only for care while the resident is restrained but should show effort to find alternative treatments to restraints, or there should be documentation in the medical record that no alternative is appropriate. An appropriate drug regimen reviews should be conducted on the resident. Your observations should show interaction between residents and staff to be, except in unusual situations, free from tension and hostility. Staff should step into situation where one resident may be abusing another.	

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F79-83 (cont'd)	**- Observe for evidence of resident neglect, residents left in urine/feces without cleaning.**	Ask Resident: - Do you feel safe in the facility? - Do you ever feel intimidated, harassed, or otherwise abused? - How are confused residents treated? - Is anyone ever hit or treated roughly? - Do you feel as if you are treated with respect /dignity? - Is the staff/administration responsive to complaints? - Do you know who to complain to?		Resident should feel free to voice complaints. If no complaints are noted in records or on record review, why not? Residents should seem comfortable in relating how they are treated?	

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
G. Privacy F84-89 SNF 405.1121(k)(8)(9)(14) ICF 442.311(g)	- Observe interactions between staff and residents for indications of respect, consideration, dignity and individuality. - How do staff members enter a residents room or go behind a privacy curtain? - Are privacy curtains used or doors shut when personal care needs and/or treatments are rendered? - Are there areas for residents to be alone or meet in private with visitors?	Ask Resident: - Do you feel that you are treated as a worthwhile, adult individual? - - When you are being cared for, are you comfortable? - What is the degree of privacy and respect you receive? - Do you feel comforatable that if the door to your room is closed staff will knock or otherwise make their presence known before entry? - Do you have a private place to make telephone calls? - - Can you see your record if/when you ask? - Has any information about your condition been given to someone outside of the facility without your permission?	Review progress notes for indications that staff see resident as an individual—i.e., resident eats breakfast in bed because he/she enjoys it. Signed consent for release of information. Do maintenance of and content of medical records indicate that confidentiality is practiced?	Observations and interviews will give you information to determine if residents are respected and treated as individuals. Is privacy available—e.g., access to a private place to meet or make phone calls, ability to shut door when having visitors, etc. Medical records should not be left where unauthorized personnel can read them and there should be identification codes needed to access computerized records. Married residents should be sharing rooms if they desire to do so unless there are appropriate contradictions.	Medical Records 405.1132(b) 442.318(d)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F84-89 (cont'd)	- Are medical records kept in their assigned spots not carelessly left for nonauthorized persons to view? - Are married residents sharing rooms? - Observe for negative attitudes toward aging-infantilization and patronizing of residents. - If residents undress in public area, how does staff handle this? - Listen to staff conversation in public places (elevator, lobby). Are resident issues being discussed?	For Married Residents: - When your husband/wife visits can you shut your door and be assured of privacy? - Can you ask that you not be disturbed and have that request respected? Ask Staff: - What is done to assure that each resident maintains his/her dignity and individuality? - How are medical records kept secure? Who has access? - Do you have married couples here? - Do they share rooms? - If not, why? - What arrangements do you make for spouses or significant others to visit? - Do you allow their door to be closed? - Can you adhere to a request that they not be disturbed? - How are residents' medical records and conditions kept confidential?			

H. Work F90 SNF 405.1121(k)(10) ICF 442.311(h)	- Are residents doing any type of work such as picking up dirty trays, pushing laundry hampers, etc.? - What about clerical work?	Ask Resident: - Are you ever asked to help out in the facility such as pick up dirty trays or stamp mail? - If yes, do you do this? - Do you want to, or do you feel it is expected of you? - Do you feel you can say "no"? Ask Staff: - Are residents asked to help with facility staff if you are shorthanded? - What is their reaction? - What useful work is available for residents who want/need to be usefully "employed"?	If residents are performing services for the facility, is that included in their care plan with specific therapeutic goals defined? If appropriate does the family cuncur? Are results documented in progress notes? What service (activities, nursing, etc.) is responsible for planning reevaluating and adjusting work activity? Look for physician's orders for approval or disapproval of work activity or restrictions on this activity. Look for evidence that the resident is given opportunities to refuse to do the work. The resident, however, is not restricted from doing the amount and type of work they desire unless it is in conflict with the plan of care.	Services performed by a resident should be part of the resident's plan of care and should be done only if the resident is in full agreement. Service rewards are specifically identified and not obtained using the residents own funds.	405.1124(d) 442.341

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
I. **Freedom of Association and Correspondence** F91-92 SNF 405.1121(k)(11) (12) ICF 442.311(i)	- **Are there areas in the facility—e.g., small lounges, etc., where residents can and do meet privately?** - **Is mail delivered opened or unopened?** - **Are facility personnel assisting residents, if needed, in opening and/or reading mail?**	**Ask Residents:** - Can you have visits from anyone? - Can you find a private place to visit? - Do you receive your mail unopened unless you request otherwise? - Are there telephones you have access to? - Does the staff or volunteers assist you in reading or sending mail, if needed? - How timely is your mail delivered? - How do you receive incoming calls? **Ask Staff:** - **Where do residents go when they want privacy?** - **What telephones are available to residents?** - What is the facility visiting policy?	Physician orders and care plans for indications of restrictions on visitors and/or receiving and sending mail.	All residents may have access to and maintain contact with the community and members of that community have access to them. Subject to reasonable scheduling restrictions, residents may receive visits from anyone they wish. A particular visitor may be restricted by the facility for one of the following reasons: - The resident refuses to see the visitor. - The resident's physician documents specific reasons why such a visit would be harmful to the resident's health. - The visitor's behavior is unreasonably disruptive of the functioning of the facility (reasons are documented and kept on file). **Decisions to restrict a visitor are reviewed and reevaluated each time the resident's plan of care and medical orders are reviewed by the physician and nursing staff or at the resident's request.**	**Resident Rights** 405.1121(k)(8) 442.311(g)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F91-92 (cont'd)	Do the available telephones accomodate the physically handicapped (e.g., wheelchair bound, hearing impaired, etc.).			Space is provided for residents to receive visitors in reasonable comfort and privacy. Telephones, consistent with ANSI standards (45.1134(c)), are made available and accessible for residents to make and receive calls with privacy. Residents who need help are assisted in using the phone. The fact that telephone communication is possible, as well as any restrictions, is made known to residents. Arrangements are made to provide assistance to residents who require help in reading or sending mail.	

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
J. Activities F93 SNF 405.1121(k)(12) ICF 442.311(j)	- What planned activities are occurring? - What unplanned activities are occurring—individual, 2 or 3 persons or a larger group. - If there is a facility chapel, is it open? - Are activities posted at wheelchair level and kept up to date? - Are residents lined up in front of a T.V. in a common room for hours? - Are activities offered during the evening and on weekends.	Ask Residents: - What do you like to do? - What did you do yesterday? (compare answers) - Is participation in activities optional? - Are you encouraged to participate? - Is pressure exerted on you to attend specific activities? - Which ones? (Surveyors should be aware of special encouragement--"gentle persuasion", which might be important for the depressed or withdrawn resident.) - Are residents notified of community activities? - Are arrangements made for transportation, etc. so that residents can participate? - Can residents go to religious services if they wish? - What opportunities are you given to make choices in your life within the facility? (eg. are all residents "put to bed" at the same time?). Ask Staff: - Are arrangements ever made to take residents to community activities? - Do friends and relatives ever take them to community activities? - Do your residents attend religious service of their choice? - How are residents kept informed/notified of activities?	Care plans or other documentation should indicate resident preferences for both facility and non-facility planned activities. Progress notes of responses to activities.	Compliance with this element is determined by evidence that residents are given the opportunity to participate in available activities they choose unless medically contraindicated. Residents must not be forced to participate against their wishes.	Patient Activities 405.1131(b) 442.345(a)(c)

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
K. Personal Possessions F94 SNF 405.1121(k)(13) ICF 442.311(k)	- Are residents wearing their own clothing or facility nightgowns, robes, etc.? - In resident rooms observe for personal belongings. - Ask residents if you can look in the closet-is personal clothing in there? - Ask residents if belongings such as clothing are identified with name tags or other identifying methods? - Is there enough space to store clothing?	Ask Residents: - What clothing and personal belongings can you have? - Is there a place that you can secure any valuables that you may not want to keep in your room? Ask Staff: - What personal belongings may residents have? - What do you do to secure valuables and other personal property? - What provisions are made for the care of personal clothing?	Admission notes on personal property inventory (e.g., the record should indicate a list of any personal property secured by the facility). The record should indicate how personal clothing will be laundered.	Residents are permitted to keep reasonable amounts of personal clothing and possessions for their use while in the facility and such personal property is kept in a safe location which is convenient to the resident. The amount that is reasonable will be dependent on space available in the facility. Patients are advised, prior to or at admission, of the kinds and amounts of clothing and possessions permitted for personal use, and whether the facility will accept responsibility for maintaining these items (e.g., cleaning and laundry). Any personal clothing or possessions retained by the facility for the patient during his stay is identified. The facility is responsible for secure storage of such items, and they are returned to the patient promptly upon request or upon discharge from the facility.	

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
L. Delegation of Rights and Responsibilities F95-97 SNF 405.1121(k) ICF 442.312		Ask Administrative Staff: - When do you have relatives make decisions for residents-i.e., how do you decide when the resident isn't capable of making decisions himself? - Have any legal steps been taken? Ask Resident and/or Guardian: - Do you feel that you are given all pertinent information? - What opportunities do you have to make decisions regarding clothing, meals, bathing schedules, etc.? - For guardian: are you notified/informed in a timely manner as appropriate?	Review physician progress notes—incapability must be documented. Is there clear documentation as to whom rights and responsibilities have been assigned? Are pertinent consents/documents signed by appointed guardian?	The fact that a resident has been judged incompetent, is medically incapable of understanding, or exhibits a communication barrier, does not absolve the facility from advising the resident of their rights to the extent the patient is able to understand them. If the resident is incapable of understanding their rights, the facility advises the guardian or sponsor and acquires a statement indicating an understanding of resident's rights. The surveyor reviews records of residents selected for indepth review who are classified either incompetent, medically incapable of understanding their rights, or have a communication barrier to verify documented evidence (signed acknowledgment) that the guardian or other sponsor has been advised of these resident rights and understand their role in acting on behalf of the resident.	Resident Rights 405.1121(k)(1) 442.311(a)

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
STAFF DEVELOPMENT F98 SNF 405.1121		Ask Residents - Does staff know how to take care of you? - What things do they do to help you accommodate your (poor vision, unsteady walking, arthritis, etc.)?	Care plans reflect staff's knowledge of the problems and needs of the residents and special adaptations that are needed. Progress notes indicate that the special needs are considered in implementing planned care.	Facility staff adjusts care to needs/problems of resident. Staff is knowledgeable concerning facility policies and procedures. Staff practices correct techniques, i.e., infection control rehabilitation nursing techniques, etc. Staff interacts and treats residents in a kind, caring way.	Residents Rights SNF 405.1121(k) ICF 442.311 Infection Control 405.1135(a)(b)(c)(d)(e) 442.327(b) Physical Environment 405.1134(a) 442.315(b)(c) 442.326(a)(c) Nursing Services 405.1124(a)(c)(e) 442.338(a)(2) Social Services 405.1130(a)
F99 ICF 442.314					
F100 1. Facility staff are knowledgeable about the problems and needs of the aged, ill, and disabled.	How do staff relate to residents? Does the facility reflect adaptations for the elderly, i.e., information given in large print, floors covered with materials that allow for ease of movement with walkers, wheel chairs, etc.?	Ask Staff - What, if any, training have you had here to learn about unique problems and needs of the aged? - What training have you had during the last 12 months? - How have you learned about facility policies and procedures? - Does the facility ask your needs when they develop a training program? - In what areas would you like to have training?			
F101 2. Facility staff practices proper techniques in providing care to the aged, ill and diseased.	Is resident care given using accepted professional standards? Is privacy maintained during bathing treatment, toileting?				
F102 3. Facility staff practice proper technique for prevention and control of infection, fire prevention	Are housekeeping staff courteous and responsive to resident needs?				

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F102 (cont'd) and safety, accident prevention, confidentiality of resident information, and preservation of resident dignity including protection of privacy and personal and property rights. INTENT To assure that facility provides ongoing training to staff so that they will be knowledgeable in current practices, use proper techniques, and interact with residents in a kind, caring way.					

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Status Change Notifications F103-104 SNF 405.1121(j) ICF 442.307 F105 1. The facility notifies the resident's attending physician and other responsible persons in the event of an accident involving the resident, or other significant change in the resident's physical, mental, or emotional status, or patient charges, billings, and related administrative matters.	Note residents condition: - Clean - Well groomed - Well adjusted - Casts - Bruises - Decubitus Ulcer - Multiple sites of edema - Aberrant behavior, e.g., abusive, disruptive, not reasonable, etc.	Ask Resident: - Have you been injured since you have been in the facility? - If you are injured or become ill, is your physician called? - Are your relatives notified? - Do you know who is notified if administrative changes such as changes in charges, billings, etc. occur? Ask Staff: - Who do you notify if a resident is injured or has a change in condition? - When would they be notified? Does the facility have a policy regarding how soon a relative or responsible party would be notified? - Do you notify them of actual changes in resident condition and also if resident's condition is getting progressively worse?	- Progress note should document injury/change in condition plus notification of physician and appropriate family member/guardian. - Changes in charges should be documented. Ask facility where this is located. - Review accident and incident reports for indepth sample.	- All injuries and changes in condition must be documented. The resident's physician and family must be notified of significant changes. This should be documented, but this notification should be confirmed by the resident if possible.	Resident Supervision by Physician 405.1123(b)(3) Emergency Services 405.1123(c)

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F106 2. Except in a medical emergency, a resident is not transferred or discharged, nor is treatment altered radically, without consultation with the resident or, if the resident is incompetent, without prior notification of next of kin or sponsor. INTENT To assure that: - the resident receives proper treatment in the event of an accident or change of condition. - resident and/or next of kin or responsible party is aware in advance of any changes. - resident is not discharged to gain a higher source payment for that bed or facility convenience.		Ask Resident: - Have you ever been or do you know if others have been transferred or discharged without discussing it with you first?	- Nursing, physician and social work progress notes should be reviewed for evidence of discussion of transfer/discharge with resident or other designated person.	- Except in an emergency, all transfers or discharges are first discussed with the resident or next of kin as evidenced by documentation in the medical record or confirmed by asking resident.	

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Physician's Services F107 SNF 405.1123 A. Medical Findings and Orders at Time of Admission F108 SNF 405.1123(a) F109 1. There is made available to the facility prior to or at the time of admission, resident information which includes current medical findings diagnoses, and orders from a physician for immediate care of the resident. F110 2. Information about the rehabilitation potential of		Ask Staff: - Interview nursing staff to determine if they receive transfer information and admission orders on day of admission. - Ask Administrator and Director of Nursing to explain procedure if a resident arrives without sufficient medical information and/or orders.	Review records of residents selected for indepth review to ascertain that: - There is a referral form from the transferring facility that was received in advance of admission or on date of admission that includes current medical findings, diagnosis and orders from a physician for the immediate care of the residents. - If the medical orders were not obtained from the residents attending physician, there are temporary orders from the emergency care physician. - Information on the rehabilitation potential (prognosis) of the resident and a summary of the course of treatment followed in the transferring facility were transmitted within 48 hours of admission. - The summary of treatment should include discharge summaries from therapies or special services when appropriate. - For residents admitted directly from the	Examine medical records of the residents selected for indepth review to determine if date of orders, medical data and other required information is the date of admission or within 48 hours of admission. The facility should receive sufficient information and orders to provide continuity of care of all residents.	

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F110 (cont'd) the resident and a summary of prior treatments are made available to the facility at the time of admission, or within 48 hours thereafter.			community, the attending physician provided current medical findings, diagnosis, prognosis, and orders. - The order should cover: + Medications and treatments + Diet + Therapies (P.T., O.T., Speech) + Activities (bedrest, ambulatory, able to participate with any specific limitations on activity).		

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Resident Supervision by Physician F111 SNF 405.1123(b) F112 ICF 442.346 B. Resident Supervision by Physician F113 1. Every resident must be under the supervision of a physician F114 2. A physician prescribes a planned regimen of care based on a medical evaluation of each resident's immediate and long-term care needs.	Observe resident for any problem/conditions that should be addressed by physician, e.g., edema, loss of appetite, weight loss, etc.	Ask Resident: - How often physician visits. - If physician has discussed plan of care and medical treatment. - If resident feels treatment and/or plan of care meets his/her needs. - What kinds of questions do you ask the physician about your health problems? (Cite examples). Ask Licensed Nursing Staff - How often physician visits and is it often enough to meet resident's need? - Does physician participate in evaluation and reevaluation of resident's plan of care? - Does plan of care meet resident's needs? - Is physician available in an emergency? - Is physician available to disucss residents treatment and care? Ask Administrator - Facility's policy regarding a physician to provide care in the absence of the resident's own physician. - Facility's policy on physician visits.	Review medical records of selected for indepth review for: - A current plan of care that is based upon physician's orders and resident needs. - Evidence that the plan is reviewed and revised as needed. - Evidence through physician's progress notes, nurses notes, physician's orders, that the physician participates in the resident's overall plan of care. - Evidence that rehabilitation potential is addressed. - Long range plans include an estimate of the length of time for skilled nursing care and a discharge plan. - Physician's orders for medications and treatments on admission and during stay. - A medical evaluation completed within 48 hours of admission unless done within 5 days prior to admission that includes attention to needs such as diet, vision, hearing, speech	Medical records should provide evidence that the residents are under the supervision of a physician by the coordination of physician's orders and progress notes with the resident's plan of care and observations of residents needs. There is evidence that the physician reviews and revises the plan of care as needed. There is evidence that physician services are available to the residents when the residents need such services. An alternate schedule for physician visits may be established if the attending physician determines that the resident need not be seen every 30 days. Justification for the decision is placed in the resident's medical record and is reviewed by the U.R. Committee and State medical review team. Where there is a change in the resident's condition and the physician has failed to document his findings or evaluation of the condition, the physician has failed to provide	

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F114 (cont'd)			level of activity, emotional adjustment. - Evidence in care plans and treatment records that physician's orders are being implemented. - Discrepancies in medication record, diet order, intake and output records. - Evidence that an alternate physician provided care if applicable. - Progress notes by physician at least every 30 days for first 90 days (ICF-at least every 60 days). - Review of medications and treatments every 30 days or 60 days if an alternate schedule of visits has been approved. - Documentation of physician observations, actions and plans for treatment. - Justification for alternate schedule of visits.	evidence of his evaluation of resident needs and supervised care.	
F115 3. A physician is available to provide care in the absence of any resident's attending physician.				A physician is available to respond within a reasonable time when a resident needs medical attention.	
F116 4. Medical evaluation is done within 48 hours of admission unless done within 5 days prior to admissions. NOT ICFs.					
F117 5. Each SNF resident is seen by their attending physician at least once every 30 days for the first 90 days after admission.			A few closed records should be reviewed to determine if residents were appropriately discharged by an order written by the attending physician. Also review	Although medical evaluation can be noted as a revision of the previous H&P A statement such as "no change" when in conflict with the status of the	

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F117 (cont'd)			discharge plans to assure that they were adequate and implemented.	resident on this admission to the facility, does not constitute a medical evaluation.	
Exception: ICF residents must be seen every 60 days unless otherwise justified and documented by the attending physician.			Verbal medication orders are countersigned by a physician. Physician is reviewing all medication orders every quarter.	Verbal medication orders must be countersigned with 48 hours.	
F118 6. Each resident's total program of care including medications and treatments is reviewed during a visit by the attending physician at least once every 30 days for the first 90 days and revised as necessary.					

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Exception: Only medications must be reviewed quarterly for ICF residents.					
F119 7. Progress notes are written and signed by the physician at the time of each visit, and all orders are signed by the physician.					
F120 8. Alternate physician visit schedules that exceed a 30-day schedule adopted after the 90th day following admission are justified by the attending physician in					

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F120 (cont'd) the medical record. These visits cannot exceed 60 days or apply to patients who require specialized rehabilitation schedules. Exception ICF residents must be seen every 60 days unless justified otherwise documented by the attending physician.					
C. Emergency Services F121 SNF 405.1123(c) F122 Emergency services from a physician are available and provided to each resident who requires emergency care		Ask Staff: - Are you aware of physician reporting procedures and medical protocols to be followed during a fire emergency? - Do you know where names and telephone numbers are of physicians to be called in case of emergency?	- If records document an accident or a medical emergency, was the patient seen by a physician or was the physician notified promptly of the emergency? - Review physician's orders to see if specific medications or treatments were ordered to treat emergency situation if applicable.	- Surveyor verifies that there are readily available written procedures for securing a physician in case of emergency. - Names and telephone numbers are posted or on rolodex. - An alternate physician is designated.	Status Change Notification 405.1121(j)

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F122 (cont'd) INTENT: To assure that a physician has overall responsibility for the managment and supervision of the residents care.			- Review physicians progress notes to see if emergency situation was addressed.	- There is provision for: + Notification of attending physician/emergency and other responsible person. + Arrangements for transportation. + Preparation of reports. + There is evidence in the medical records that proper procedures have been carried out. + Residents with sudden changes in condition have been evaluated by the physician.	

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Nursing Services F123 SNF 405.1124					
F124 SNF 405.1124(c) F125 F126 ICF 442.1124(c) A facility provides nursing services sufficient to meet nursing needs of all residents all hours of each day. F127 Grooming and Personal Hygiene SNF 405.1124(c)	Basic care provided to residents: Surveyors should observe the basic care provided by staff to the residents. Listed below are suggested areas of attention which may provide evidence of the quality of personal care: - Eyes/Ears/Mouth Presence/absence of: + Secretions forming around eyelids, redness or irritation of eyes. + Eyeglasses worn when appropriate are clean, in good repair and fit properly. + Backs of ears scaly, obvious wax build-up, discharge, odor. + Hearing aid worn when appropriate, is in good repair and working. + Dried food particles or drool, etc. around mouth.	Ask Resident: - If the resident's clothing is inappropr-ate, ask: + Did you choose your clothing today? + Is this what you want to wear? + Do you have other clothing available? - If the resident is not clean, poorly groomed, or inappropriately groomed, ask the resident: + Have you had any help in caring for yourself today (e.g., washing your face, brushing your teeth, etc.)? + How often do you have a bath/shower? + How often is your hair washed? + How often do you brush your teeth/ clean your dentures? + Were there extenuating circumstances (e.g.,	Nursing notes, flow sheets or bathing records should indicate that the care plan for grooming and personal hygiene is being followed. For example: - Bathing schedules are being followed (including the use of any soaps or special lotions). - Assistance instruction and/or supervision is being provided as identified for each activity. Nursing documentation should also indicate resident response or any changes in the resident's behavior, reaction to an activity, or the ability to carry out grooming and personal hygiene activities. Look for indications of progress toward a goal or further deterioration of resident functioning.	Refer to information on observation. A pattern of evidence of poor personal care indicates noncompliance unless the care plan specifically deals with this and appropriate planning and implementation is occurring. The regulations require that individual preferences are taken into account when providing for grooming and personal hygiene and that residents are encouraged in self-care activity. Do your patient interviews substantiate compliance with the regulations?	Resident Rights 405.1121(k)(8)(13) 442.311 (g)(k) Social Services 405.1130(a) 442.344 Activities 405.1131 442.345(a)(c) Patient Care Management 405.1124(d) 442.341 Training 405.1121(h) 442.314

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F127 (cont'd)	+ Dentures worn when appropriate and in good repair. + Oral hygiene. - Odors presence/absence of: + Body odors - Hair/Scalp + Clean and free of rashes + Hair combed - Nails are clean and appropriate length - Clothing is appropriate, clean, and in good repair. + Extremities elevated as necessary while in chair or wheelchair. + Appropriate techniques to prevent infection. + Use of whirlpool as a treatment modality as available and appropriate. - With resident's permission check: + heels, feet and toes + lateral hip + scapular area + sacrum + buttocks + bony prominences in contact with braces + condition of stump (especially diabetic	resident is participating in dressing retraining program)? - Special consideration might be given to the demented patient who frequently "borrows" clothes and for whom removal may elicit catastrophic reaction-whether clothing "matches" may not be the most important issue in the care of these patients. Ask Direct Care Staff: - How do you choose what clothing each of your residents wear each day? - Do you have a specific schedule for washing residents' hair? - How did you learn to bathe resident? - How did you learn to wash residents hair? - How did you learn to shave residents? - How do you handle situations when residents want to wear dirty clothes, or mismatched clothes? - How much care do you let the residents do on their own?			

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F127 (cont'd)	amputees with elastic bandage or sock removed).				
Skin Condition F128-129 SNF 405.1124(c)	Observe with residents' permission: - General condition of skin + Redness + Blanching + Soft/dry/rough etc. + Rashes/irritation + Bruises + Scabs + Free of above - Measures taken to prevent skin breakdown. - Pressure sores - Pressure sores Rx - Factors contributing to prevention of pressure sores + Overall cleanliness and maintenance of dry and aerated skin (uncompromised by urine/feces/perspiration) + Padding for pressure points and bony prominences including padding on bed/chair + Proper gentle massage to bony areas several times a day.	Ask Resident: - Are your feet usually swollen? - Do you know what causes the swelling? - What do you do to alleviate it? - Is this discoloration normal for you? - How did this wound/bruise develop? - Are the treatments done about the same time every day? - What staff person has looked at your skin recently?	Look at nursing notes and P.O.C. for evidence of: - Planned preventive measures - Treatments/Intervention including nutrition - Routine assessment/evaluation of skin condition - Documentation of specific skin problems with location number, severity, measurements as appropriate, and cause - Progress or lack of progress in healing - Assessment/Reevaluation of interventions with alterations in plan - Appropriate nutritional plan - Methods to control edema of lower extremities	Preventable pressure sores are not occurring. Ulcers present are treated on a routine basis according to P.O.C. Is skin clean? Is resident dry? Is turning schedule adhered to? Are linens clean and smooth? Do personnel know preventive measures and practice these? Has a nutritional assessment been done, and if appropriate, recommendations implemented?	Dietetic Services 405.1125(i)(c)(e) 442.332(a)(1)(b)(i) Activities 405.1131(b) 442.345(a) Patient Care Management 405.1124(d) 442.341 Training 405.1121(h) 442.314 Rehabilitative Nursing 405.1124(e) 442.342 Supervision of Patient Nutrition 405.1124(f) 442.332(b)(2)

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F128-129 (cont'd)	+ Regular assistance for resident to turn or shift weight (bedrails, footboards, trapeze). + Bed linens, clothing, underpads smooth and free from wrinkles. + Elastic bandages or hose are smooth and wrinkle free. + Elastic bandages wrapped smooth with appropriate overlap. + Dietary/nutritional support for skin integrity. (See Guidelines for Dietary/Nutrition + Prevention of shearing force when resident's position altered by staff. + Turning and repositioning as needed. - Care and Treatment: + Turning and repositioning every two hours or as needed (e.g., alternative approach that is justified by the facility.) + Positioning of the ulcer site or protection of affected areas. + Use of effective pressure relief devices.	Ask Direct Care Staff: - What can you tell me about Mr./Mrs. ______ swollen feet/wounds/ brusises/etc.? - What do you do for them? Ask Charge Nurse: - How did ______ get cuts, bruises, etc.? - What is being done to prevent further occurance? - What treatment is he/she receiving?			Resident Supervision by Physician 405.1123(b)

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Wounds/Wound Dressings F126 SNF 405.1124(c)	- Condition of dressing - i.e., clean, firmly secured unless contra-indicated. - Observe, if possible, and with resident's permission, a dressing change + Pre-dressing Removal Equipment and supplies organized Hands washed Residents provided with privacy - Dressing Is: + Old dressing observed for drainage? + Wound examined + Appropriate technique used + Proper disposal of old dressing? + Post dressing + Does staff member wash hands? + Return resident to comfortable position or previous activity?	Ask Resident: - How often is the dressing changed? - By whom is the dressing changed? - Does it seem dressing changes are frequent enough? - Are there any odors from the dressing? - Is the dressing change always done in a similar way? - If not, what are the differences? - Do you feel confident that the wound is being well cared for? - Is the area/wound healing? - What caused the ulcer, wound, etc.? Is it healing? Does the staff keep you informed of its status? Ask Staff: - Specific treatment and schedule for each resident?	- Physician orders for wound care - Progress notes detailing condition of wound - i.e., size, drainage, surrounding tissue, odor - Treatment provided - Progress/change - Plan of Care (POC) + The plan of care should address: - Area in need of treatment, treatment to be performed, frequency, and responsible staff. - All necessary solutions, ointments, irrigations, types of dressings, and materials. - Any necessary precautions, drains, if present, sutures and tubing. - Specific goals of treatment as well as any problems or limitations imposed as a result of treatment.	Physician orders, your observations, progress notes and POC should reflect the same information. Treatment provided over a period of time with no improvement and no re-evaluation also would represent non-compliance, unless nursing/physician progress notes address the "no improvement" problem. Compliance is evidenced by: - treatment given according to doctor's orders and POC. - use of appropriate technique when caring for wound/changing dressing (e.g., follows facility's written procedures). - periodic evaluation of healing process and revision of care plan as needed.	Physician Services 405.1123 442.346 Infection Control 405.1135(b) Pt. Care Management 405.1124 442.341 Dietetic Services 405.1125(b)(c)(e) 442.332(a)(1)(b)(1) Medical Records 405.1132 442.318

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Restraints F130 When residents require restraints the application is ordered by the physician, applied properly, and released at least every two hours. (See also information under Resident rights-freedom from abuse & restraints)	Direct to evidence of: - Proper application - Proper use - Maintenance of good body alignment - Resident observation, release and exercise Observe frequently throughout your visit to validate care. Specific observations should include the following items: - Type of restraint: belts, wrist or ankle cuffs, blanket restraints, vests, bed nets, locked, etc., (When locked restraints are used can you readily find the key and/or scissors?) as well as geriatric chair or geri-table/tray in place for prolonged periods. - Protective devices and/or safety devices that are used as restraints must be evaluated as restraints. - Appropriate application: skin protected from injury (restraint neither too loose nor too tight to prevent	Use of restraints may be precipitated by an "emergency" situation in which there is a threat to the resident's health or safety, or a threat to the health and safety of others due to the resident's behavior. Restrained residents may not be coherent or rational enough to respond to questions and caution in interviewing therefore, must be exercised. However, observation of a resident in a geri-chair with table in place or a resident in a wheelchair (with vest restraint) for several hours would warrant appropriate questions as to when the staff last assisted him or her to move about or whether the resident would like to get out of the chair. Staff interviews focus on the reason why the resident is restrained. Ask Direct Care Staff and Charge Nurse: - When, why, and how to release and apply restraints? - Why is the resident	- Physician orders for restraint: reason, length of time, type - Progress notes - Describe the resident's status/behavior which prompted the use of the restraint. - If a chemical restraint, the order should indicate a specific time period for its use as well as a stop date. - Plan of Care should + Identify other methods or therapies that are being used in conjunction with restraints. + What alternatives to restraints have been considered. + Identify staff responsible for observing the resident (every 30 minutes), and releasing and exercising the resident (every 2 hours for at least 10 minutes). Time intervals should be identified. + Indicate involvement and input of other disciplines necessary to overcome the problem. + Indicate a specific period of time for	- Is there a physician's order, including the circumstances in which they will be used, the length of use, and the type of restraint? - Is the restraint applied properly? - Is it released at least every two hours and the resident provided with exercise and toilet facilities if needed? - Does the staff observe the resident frequently while he/she is restrained? - Are chemical restraints administered in accordance with physician's orders? - Is the order for restraints renewed only after a reassessment of the patient?	Patient Rights 405.1121(k)(1)(7) 442.311(f)(2)

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F130 (cont'd)	rubbing and blistering or impeded circulation) - Body alignment and support: use of pillows, footboards, and wheelchair footrests to maintain appropriate posture, circulation, and to prevent skin injury or breakdown. - Periodic release and exercise: exercise may include ambulation, range of motion, massage, or other opportunities for motion (at least 10 minutes every 2 hours during day and evening hours). - Chemical restraints: residents appear drowsy throughout the day (may indicate tranquilizers or other drgus are being used to limit or control behavior for staff convenience).	restrained? - Was the resident given an option of restraint? - When were you taught the use of restraints? By whom? - If chemically restrained (excessively sedated) + Why is this done? + Whether alternate means of restraint have been attempted, for how long this will continue, etc. This should elucidate from staff whether the chemical restraint is necessary, or whether it is done for staff convience by controlling resident behavior - Do you ask the resident for permission before using restraints? - How does the restrained resident summon assistance? - What is the usual timeframe for assistance to reach the restrained resident? Ask Resident: + Why are you restrained? + What would happen if the restraint were removed? + When do you use bed rails? + What purpose do they serve? + How do you gain assistance?	using the restraint. - Indication of assessment of factors which precipitate residents behavior which has warrented restraints and plans to intervene early enough to prevent occurence. - Type, duration and frequency of exercise should be documented. - An assessment of why restraints are continued should be documented.		

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Bowel and Bladder F131 SNF 405.1124(c) Each resident with incontinence is provided with care necessary to encourage continence including frequent toileting and opportunities for rehabilitative training.	- There should be a chart/record in the resident's room on which the program is documented accurately. - If the room is located a distance from the toileting room or for residents with problems ambulating, a commode may be present in the room. - Verify that a call light is available to the resident if non-ambulatory or re-strained. - Are fluids available at bedside? - Is there roughage on meal tray? - Diet is appropriate to enhance elimination?	Both the resident and direct care staff should be interviewed and should exhibit a good understanding of the importance of maintaining a regular schedule of elimination. If neither are aware of the intake and toileting schedule, then determine whether they are appropriately panning the resident or carrying out a retraining program. - Verify that the resident is aware that he/she is on a retraining program and knows the content of the program. Ask Resident: Suggested questions are: - How do you deal with constipation/diarrhea? - Are you involved in a special bowel/bladder training program? - If so, how does your program work? - Any problems with it? - Any successes to date? - What does the staff do for you in this matter? - Are they consistent and timely? - How long do you have to wait to be taken to the toilet?	- Physician orders if required by facility policy - Nursing notes for + Assessment + Documentation of techniques and progress, reevaluation - Plan of care The plan of care should clearly address: + Goals that resident will aim for. + Methods to accomplish the goals. + Schedule for fluid intake. + Schedule for toileting. + Responsible staff + Any limitations the resident may encounter as a result of either incontinence or the training program. - Progress notes/physician orders for cause of incontinence. - Laboratory tests of kidney function when available - Treatment for diarrhea/constipation - Residents preference for treatment of constipation. - Recently admitted and newly incontinent residents should be thoroughly assessed for at	- Are all incontinent patients assessed for cause of incontinence and ability to be helped by a bowel/bladder rehabilitative training program or an incontinence management program? - Are all appropriate residents involved in bladder/bowel training programs or, incontinence management and there is a schedule that shows when the program will be started? - Is there evidence of follow through on all shifts? - For residents not on bowel/bladder retraining programs the plan of care should address specific measures for managing incontinence with a view to prevention of skin and other problems and maintenance of resident dignity.	Nursing Services 405.1124(e) Dietetic Services 405.1125(c)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F131 (cont'd)	- When a resident puts on his/her call bell for toileting assistance, how long is it before assistance is given/ - Observe pre-meal toileting. - Privacy provided. - Schedule for toileting should allow for resident's normal sleep pattern, to avoid disrupted sleep.	Ask Nurses Aides and Charge Nurse: + Will you describe this resident's bowel/bladder (B/B) training program? + How long has it been in effect? + When will you evaluate the results? + If this program is not successful - What assessment was done to determine B/B status - For residents not on B/B retraining programs what is the facility program for managing incontinence?	at least 7 days for the cause of incontinence and when appropriate an intensive bowel and bladder B/B training program should be instituted. - A trial B/B training program is suggested for all residents with incontinance problems. - I & O		
Catheter Care F132 SNF 405.1124(c) Each resident with a urinary catheter receives proper routine care including periodic evaluation	The indwelling catheter should promote a continuous flow of urine unless ordered otherwise. The surveyor should also observe for the following: - Ample supplies for catheter insertion and care. - Proper positioning of the tubing and drainage bag. - Cleaniness of the	Ask Resident: - What is the tubing/cathetor for? - Why do you have one? - Does it cause any discomfort? - If it does, what is done about it? - How do you feel about having the catheter? - Is any special care given in relation to the catheter?	The surveyor should verify that there is a physicians order for an indwelling catheter, including the type and frequency of catheter care. If irrigation is ordered, the order should include type of solution and frequency of irrigation. The record should also indicate the color, consistency, and amount of urinary drainage.	*The facility should follow accepted professional standards in their catheter care. There should be medical reasons for catheter insertion - staff convenience cannot be justification. Direct care staff should know signs and symtoms of urinary tract	Infection Control 405.1135(b)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F132 (cont'd)	tubing and drainage bag. - Color and consistency of urine in bag. - Availability and accuracy of documentation on the I&O sheet if ordered or policy. - Proper equipment for ambulation - leg bag if resident is ambulating. (if ordered) - Availability of fluids. - When indicated monitor intake to ensure adequate intake and output or conformance with physician orders. - How many observed residents are on catheter care?	Ask Nursing Aide and Charge Nurse: - How do you routinely position and secure catheters and drainage bags? - How often is each part of the system changed? - What are the indications for insertion of the catheter? - What is the facility's procedure for routine catheter care? - How do you observe for U.T.I.'s in residents with indwelling catheters? - What is the facility's procedure for the cleansing and storage of reusable catheter equipment and drainage receptacles? - How do you care for catheter tubing?	- Assessment should address: + Need for an indwelling catheter. + Resultant problems or limitations. - Plan of Care should address: + Type of catheter and type and frequency of care. + For irrigation, the rationale, the type of solution, amount, and frequency of irrigation. + Frequency of symptoms which would precipitate catheter change. + Time frames of catheter change and responsible staff. + Appropriate increase in oral fluid intake. - Intervention The record must reflect: + When and by whom the catheter was inserted and for what reason. + Any special care provided + New problems or changes + Only appropriately trained staff should deliver catheter care. + Only licensed staff should insert	infections (U.T.I.s) and these should be reported and treated promptly. *The Center for Disease Control has developed standards for catheter care which may be used but it is not a requirement.	

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F132 (cont'd)			indwelling catheter. + The specific type and size of equipment used should be noted. + Signs and symptoms of urinary tract infections (UTI) should be acted upon and documented as to follow-up. - Evaluation/Reevaluation The record should reflect that the resident: + Is assessed for UTI. + Has no abdominal distention. - Notes should also include: + The color and odor of urine and the development of any problems after insertion of indwelling catheter. + Verify that catheter is patent.		

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCES
Injections F133 SNF 1124(c)	- Observe for preparation of injection - i.e maintenence of sterility; correct dilution, handwashing, before preparation, etc. - Observe injection site for: + Redness + Discoloration + Swelling + Lesions - Observe for proper technique when injection is given + correct site + correct needle size + correct volume of drug + sterility maintained - Resident is observed for any adverse reaction - What is the disposal method for used needles or syringes?	Ask Nurse: - What is your plan for alternating injection sites? Show me. - What is the medication for and what are potential adverse reactions? - Is there nonspecific pain at the injection site or shooting pains down a limb? - Is there skin irritations or lumps under the skin? - If adverse reaction occur, how soon are they reported? - Could this be given by any other route? Ask Resident: Suggested questions are: 1. What kind of medicine do you receive by injection/shot? Why do you need that medicine? 2. Do you have pain or numbness at or around your injection site? 3 Who gives the injection? 4. Do you receive your injection according to a schedule?	- Physician order sheet - Nursing notes for: + Resident response to medication if appropriate + Any problems noted at injection site + Any other adverse reactions + Site of injection - Plan of care + Rotation of injection site + Care for any special problems related to the injection. - Infection Control: reports for any infections connected with injections.	- Is the medication administered according to the physicians order? - Is proper technique used in preparation and administration including site rotation? - Does the nurse administering the medication know the expected action of the drug? - If infection control reports show infections at injection sites. - Is the resident's response to the medication noted in the progress notes?	Staff Development 405.1121(h) 442.314 Infection Control 405.1135(b)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCES
Parenteral Fluids F133 SNF 405.1124(c)	The surveyor should observe that parenteral fluids are administered with safe, aseptic technique providing fluids as ordered by the physician. Safety and comfort measures are to be taken insuring maximum protection and optimum hydration of the resident. The surveyor should note the following items: - Labeling of the solution bottle/bag. - Rate of infusion/cc/ml per hour. - Date and time started --additives, if any. - Any signs of swelling or redness at site. - Site dressing is clean, dry and dated. - Accurate I&O of parental and P.O. fluids - If splint (armboard) is used, it is applied to prevent movement but not impede circulation. - Positioning of I.V. tubing. - Comfort of restraint used to allow for maximum resident freedom while preventing movement of I.V. site.	Ask Resident: - Why do you have this tube in your (arm)(leg)? - Is it comfortable? - Is there a way it would be more comfortable? - How long has it been in? - How much longer will it stay in? Ask Appropriate Staff: - Why the resident is receiving I.V. therapy? - What the drip rate is (the amount of fluid to be received per hour). - How often the dressing is changed. - How often the tubing is changed. - What are possible side effects? - How often is the site changed? - How often is the infusion checked for drip rate and the remaining volume to be administered? Ask Nursing Aide - What are your responsibilities when caring for a resident receiving IV fluids? - What training have you had?	- Physician's order for parental therapy specifying type of fluid, rate of infusion/hour, and additives, if any, is available and current. - Twenty-four hour I&O record. - Nursing documentation indicates physician's orders are being followed. - Any adverse reactions are noted in the medical record. - Record indicates: + Infusion started by whom; cite time, rate of flow + Note is made of observation of pain or swelling at infusion site. + The need or reason for parenteral fluids. + Response to the therapy. + Problems and limitations encountered by the resident as a result of receiving parenteral fluids. - Plan of Care* The plan of care should include + Type, rate of infusion /hour, and additives (if ordered).	- Is the parenteral fluid administered according to the physician's order and in accordance with accepted nursing practice? - Are infiltrations noted in a timely manner before a large amount of fluid infiltrates? - Is the facility procedure for care of the IV site and tubing changes followed for all patients unless contraindicated? - Does documentation reflect what the patient received, any problems, and his/her response to the parenteral fluid? - Have any adverse effects been caused by administration of IV fluid? - If yes, were these preventable?	Resident Care Policies 405.1121(1) Infection Control 405.1135(b) Patient Care Management 405.1124(d) 442.341

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F133 (cont'd)			specified goals for correction, time frames, and responsible staff. - Documentation must include time administered and by whom, the amount of fluid infused, and any other special care administered as a result of IV therapy (i.e., mouth care, assistance with ADLs, etc.). - The record must reflect: + Conditions of site and any infiltrations, phlebitis, necrosis, etc. noted, along with measures taken to correct these. + The resident's response to therapy + Changes in laboratory studies *Plan of care would not be modified for a one-time IV infusion.		
Colostomy/Ileostomy F133 SNF 405.1124(c)	The surveyor should ascertain that the facility is providing appropriate nursing care to those residents who have had bowel surgery resulting in a colostomy or ileostomy. It is recommended that the surveyor, with the resi-	Ask Resident: - Why was the ostomy performed? - How do you feel about the ostomy? - Does it ever cause you problems (e.i., pain, skin problems, odors accidents)? If so, what	The surveyor should determine that: - Colostomy irrigations, if ordered, are documented as performed by the resident or appropriately trained staff. - In the case of sigmoid colostomy regular patterns of bowel elimination are	Compliance would be indicated if residents are physically and emotionally comfortable with the ostomy with minimal or no skin problems. If residents are not comfortable with the ostomy, are having skin or other problems, the facility	Patient Care Management 405.1124(d)

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Colostomy/Ileostomy F133 (cont'd)	dents permission, observe care being given to determine that proper techniques are being used. The following steps should be taken to assure that proper ostomy care is being provided. - The ostomy dressing should be changed or the bag emptied and thoroughly cleaned promptly after each bowel evacuation or more frequently, if drainage continues. - The peristomal skin should be cleansed and dried, and appropriate measures taken to prevent excoriation and infection. - The resident's privacy should be considered while providing care. - The resident should be provided with information and instruction in self-care at the appropriate level of understanding. - The resident should be observed for signs of withdrawal, disgust anxiety, or other emotional responses which may be related to his/	does staff do about it? - What does the staff generally do with or for the ostomy? Are they consistent and timely? - Has staff talked to you about doing some of the care for this? If so, what was the outcome? If not, is this something you'd be interested in learning more about? Ask Staff: - If nurses aid: + How did you learn to take care of colostomies? + What do you do if the skin around the colostomy becomes red or sore? + Do you ever teach the residents to care for their own colostomies? - If nurse (RN or LPN) + What is the procedure if the resident becomes constipated? Ask Other Nursing Staff: - Is there a facility procedure for ostomy care? - Do you have skin problems with your	documented as established through management of diet, fluid intake, exercise, and the use of prescribed laxatives, suppositories, and/or irrigations. - Ostomy care is documented in the resident's record along with a description of the excreta. - Problems in irregularity, skin breakdown, or other observable concerns are documented and reported to the physician. - Documentation indicates that nursing measures are taken to assist the resident who is experiencing problems in understanding and/or accepting the presence of the ostomy. - Documentation of nursing measures to maintain skin integrity. - Assessment The assessment should indicate: + Needs, problems, and limitations as a result of an ostomy. + Specific degree of	should be responding to these and correcting them as reasonable. Care plans should indicate specific goals in relation to problems and specific interventions for reaching these goals. When available an enterostomal therapy nurse should be involved in developing the care plan for residents with urinary and intestinal stomas.	

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Colostomy/Ileostomy F133 (cont'd)	her acceptance of the colostomy/ileostomy. - The surveyor should observe the staff giving ostomy care to verify that proper technique is used.	ostomy residents? - What do you do when skin becomes excoreated? - What teaching do you do with the residents? - What in general is the response to this teaching?	self-care performed or assistance needed. + Special skin care needs. + Special dietary needs. + Emotional support. + Medications and treatments if needed. - Plan of Care The plan of care should clearly address: + Specific goals to overcome or improve the problems(s) identified. + Methods to accomplish the goal (training, assistance, supervision, treatments, emotional support). + Services necessary and who will perform the services. + Time frame for accomplishing goals.		Social Services 405.1130(a) 442.334(a)(b)

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Respiratory Therapy F133 SNF 405.1124(c)	- Aerosol Compressor or IPPB (Intermittent Positive Pressure Breathing Machine) The surveyor must determine that the facility is providing respiratory therapy as ordered by the physician. Observation for this indicator should focus on the necessary equipment as well as on the resident. In order to determine that the necessary equipment is available, the surveyor must look for the following: + Aerosol compressor or IPPB Machine. Check that the machine is clean and operable. + Tubing - If tubing is not attached to the machine, ask to see it. Check that it is stored dry and with consideration for cleanliness. + Nebulizer Cup - should be attached to tubing. It is filled with either the prescribed medicine or distilled water only if about to be used. It should not be	While interviewing the resident, observe for sounds of congestion. Note color of lips and nail beds. Ask Resident: - Do you ever feel short of breath? - If yes, what is done when this occurs? - Is the therapy helping you to feel better? - Are there any problems with it? - If so, how does the staff respond? - Is the therapy consistently performed - both concerning time and method of providing it Ask Staff: - What is the reason the resident is getting this therapy? - What are the expected results? - Can you demonstrate how you use the equipment? - How often is the equipment cleaned? - What are the infection control procedures in regard to use of res-	The surveyor should determine that: - Respiratory/oxygen therapy is performed or administered by appropriately trained staff. - There is a physician's order for therapy, and it is specific as to rate of delivery, etc. - If the physician's order is for prn therapy, it should specify for what symptoms. - Any information gained from resident or staff is verified in the record. - Assessment + The assessment should address both the need or reason for therapy and any problems or limitations which result from the need for therapy. - Plan of Care The surveyor should note: + The kind, amount, frequency, and/or duration of therapy based on the physician's order. + Specific goals to overcome to improve any identified	Only qualified (trained) personnel should administer/assist with respiratory therapy. Therapy must be provided as ordered. The effectiveness of the therapy must be periodically evaluated and therapy revised as appropriate. Effective infection control measures must be practiced. Needed safety precaution for the use of oxygen must be practiced. Equipment should be available and in working order.	Staff Development 405.1121 (h) 442.314 Infection Control 405.1135(b) Patient Care Management 405.1124(d) 442.341

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Respiratory Therapy F133 (cont'd)	stored wet. If it is not attached to the tubing, ask to see it. The mouthpiece is connected to the nebulizer cup. The surveyor should also check that all involved equipment is clean. - Oxygen Therapy The surveyor must establish that the facility is meeting the oxygen needs of the resident. When the facility does not have wall units, check that: + There are enough cylinders for oxygen delivery. + There should be flow meters and regulators for tanks in use. + A wrench should be attached or stored close by. + If using large cylinders (size G or H), look for a carrier since these tanks cannot be transported without it. + The cylinder at the resident's bedside should either be on	piratory equipment? - What training was given you in the use of this equipment? - Where is the emergency oxygen supply?	problems and/or limitations. + Specific methods to accomplish the goals (observation, supervision, training, etc.). + Who is responsible to perform therapy or assist in accomplishment of goal. - Intervention - The record should display evidence that: + The plan of care is functional + The therapy was admin-administered in accordance with physician's order for the specified reason(s) by an appropriately trained staff member + Change in condition is tion is documented and acted upon promptly. - Evaluation/Reevaluation The record should reflect: + The resident's response to therapy. + If response was undesirable, evidence of further intervention. + Any progress, deterioration, or development of new problems.		Physical Envionment 405.1134 (i) Medical Records 405.1132 442.318

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Respiratory Therapy F133 (cont'd)	the carrier, sitting on a metal skirt, or otherwise secured. + There should be other necessary equipment available such as humidifiers, nebulizers, masks, nasal cannulas, T-pieces, etc., all should be dry and clean when stored. + Check to see that non bed-bound residents are not limited to their own chair/room when using oxygen (portable units will prevent social isolation. + Water reservoir is appropriately filled per manufacturers instructions. + Check to make certain the tank is not empty and that any tank is labeled as such. + Check for good oral hygiene of resident. + The room should be posted with a "No Smoking" sign. - Residents on respirators: + Are alarm systems turned on?	Residents on Respirators Ask Staff (all levels): - What training have you had in caring for	+ Based on the above information, possible modification of goals.		

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Respiratory Therapy F133 (cont'd)	+ Is sufficient Oxygen supply available? + Is the ventilator accessible to an emergency outlet? + Is the resident in a location that allows for frequent observation by staff? + How does the resident communicate with staff? + What level of staff (aide, LPN, RN) caring for the resident? + Is such equipment at bedside? + Is there reserve back-up equipment? + What is the condition of the residents skin around intubation tube/tracheostomy. + Does the care given use appropriate technique in caring of the patient?	residents on respirators? - Can you show me how the alarm system works? - What is your procedure for pulmonary care? - What is your procedure for changing tubing and the water reservoir? - What happens if the power goes off?			

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Tracheostomy Care F133 SNF 405.1124(c)	Satisfactory tracheostomy care is a procedure which promotes a clean, unobstructed air passageway and maintains the skin integrity surrounding the tracheostomy site. The surveyor should determine whether: - Adequate supplies are available for the care of the tracheostomy such as tracheostomy kits, hydrogen peroxide, normal saline or sterile water, suction machine, catheter, sterile gloves, and clean dressings. - The resident is breathing without difficulty and is comfortable. - The dressing is clean, dry, and intact; the cannula is clean, in the proper position, and secured. - The skin surrounding trach is clean and dry with no redness or inflammation. - The resident has adequate oral hygiene. - An extra tube, the same size as the one in	Resident interviews must be guided by the resident's communication ability. Ask Resident: - How long will you have it? - What care can you do for yourself? - What do you need help with? - Who helps you? - Is someone always available to suction him/her when needed? - Is the suction equipment always available in working order? - Is the dressing kept clean and comfortable? - Is the tube kept clean and changed as needed? - How often are the tubes and dressings changed? - Does he/she feel confident in the personnel caring for his tracheostomy? - What is communicating with staff and other residents like? - Are staff patient and do they allow you enough time to express your needs/thoughts/feelings? [- May I observe your tracheostomy care?] Ask Staff: - Why does resident have	- The surveyor should determine that tracheostomy care is done as scheduled and as needed following the proper procedure. - Any special solutions that are needed should be addressed in the physician's orders. - Assessment - The record should reflect that the need for tracheostomy care was assessed in terms of: + Frequency + Skin integrity surrounding the tracheostomy, noting redness, inflammation, and/or excoriations. - Plan of Care should include: + Specific times of trach care and the responsible, appropriate trained person performing this task. + Specific problems relating to skin and breathing as well as the goals set to overcome these problems listing the appropriate personnel responsible. + Time frames for resolving problems	Stoma and surrounding skin should be in good condition and if not, there should be treatment directed to resolving this problem. All staff caring for the tracheostomy must be trained and emergency procedures must be known. All needed equipment must be available and in working order. Resident must at all times have readily available a means of communicating with the staff in an emergency.	Infection Control 405.1135 (b) Training 405.1121(h) 442.314 Patient Care Management 405.1124(d) Physicians Services 405.1123(b) Social Services 405.1130(a)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Tracheostomy Care F133 (cont'd)	place, is available at bedside. - Does resident have an adequate method of communicating with the staff? - Does staff allow enough time for residents to communicate?	tracheostomy? - What training were you given to enable you to care for tracheostomies? - What is the procedure for tracheostomy care? - How often is the tube changed? - What do you do if the tube comes out? - May I watch you do a dressing change? - If not convenient, describe what you do. [- How do you communicate with a tracheostomized resident?]	listed in goals. + Plan for periodic assessment of appropriateness of residents own self care re: teaching or nursing assuming more responsibility as appropriate. - Intervention - The surveyor should look for documentation of: + Trach care and oral hygiene administration, including responsible personnel, time and date, and effects. + Any problems or changes noted in resident condition (e.g., redness, swelling, tracheal obstruction). + Emotional response to tracheostomy. - Evaluation/Reevaluation + Resident is or is not benefiting from trach care and skin care. + If problems are noted, the progress notes and plans for care should indicate changes in treatment. + Resident's emotional response to care of the tracheostomy should be evaluated.		

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Trachoestomy Care F133 (cont'd)			since this may require additional care planning.		
Suctioning F133 SNF 405.1124(c)	Suctioning is necessary for any resident who is unable to cough up secretions that are obstructing his airway. Suctioning may occur via the oral or nasal route, or stoma route with sterile technique. Attempts should be made to observe a resident being suctioned should such an opportunity arise. If so, observe that a clean/aseptic technique is observed throughout and that the resident tolerated the procedure. There should not be bloody aspirant, cyanosis, or bronchospasm. Check that equipment is in good working order, frequency of procedure, etc. Resident observations which indicate need for intervention include: - Secretions are draining from a resident's mouth or trach and the resident is unable to	Ask Resident: - How are you feeling now after the suctioning? Does the suctioning seem to help? - Has staff explained to you the need for suctioning? Why do you need to be suctioned? How often? - Who performs the suctioning (i.e., nurses or nurses aides)? Do you feel safe with the staff performing the suctioning? - Does everyone do it about the same way? Ask Staff: - When and where did you learn to suction? - Tell me what procedure you use when you suction a resident. - Do you always have enough suction machines and catheters? - How frequently is suction tubing changed? - What provisions do you have for suctioning if the electricity is lost?	- Assessment - The record should reflect that: + The resident is frequently observed for suctioning needs. + Any limitations a resident has as a result of his suctioniong needs should be specifically noted. + Any problems resulting must be specified. - Plan of Care should include: + Awareness of the resident's suctioning needs, goals, approaches, and responsible staff needed to improve the problem or at least to maintain the resident at his present status without further deterioration. The plan must clearly indicate specific approaches towards: - Prevention of skin problems around the trach if one exists. - Correction of any existing skin pro-	- All equipment must be available and in working order. - All staff caring for the resident must know what to do in an emergency. - Current professionally accepted standards of care must be maintained.	Infection Control 405.1135(b) Patient Care Management 405.1124(d)

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Suctioning F133 (cont'd)	cough or clear himself. - There are audible crackles or wheezes and/or diminished breath sounds. - The resident is dyspneic. - Restlessness or agitation may also be an indication that suctioning is needed. Upon completion of suctioning above symptoms should, in most cases, be relieved. The surveyor should observe that the resident is positioned to facilitate breathing (usually at a 45 degree angle). Check to see that the facility has an ample supply of suction machines and suction catheters to meet the needs of residents requiring them and that they are clean and properly stored.	- Where are your emergency electrical outlets? - What is your procedure for disposing of the secretions from suctioning? - How often does Mrs./Mr. need to be suctioned? - May I observe you when you suction Mrs./Mr.?	blems. - Provision of good oral hygiene including a rigid schedule for mouth care, schedules, or procedures for maintaining clean equipment at bedside, as well as disposal of used (dirty) equipment. - Route of suctioning (i.e., oral/nasal/trach). - Intervention - The record should indicate clearly that: + The plan of care is being implemented. Documentation should reflect: + The number of times the resident required suctioning, for what specific reason, and by whom the resident was suctioned. + Any special treatment the resident received in conjunction with suctioning		

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Suctioning F133 (cont'd)			(i.e., oral hygiene, skin care, etc.). - Evaluation/Reevaluation The record should reflect: + How well the resident tolerates suctioning procedures. + Any bloody aspirant, cardiac arrhythmia, cyanosis, or bronchospasm. + Further interventions utilized to overcome or improve these. + The amount of sputum as well as its color and consistency. + Any progress or lack of progress, deterioration, and/or the development of new problems. + The evaluation should determine whether goals are being reached or if new goals must be addressed.		
Tube Feedings F133 SNF 405.1124(c)	- Staff use proper technique in administering feedings and medications. Check to see that staff checks for location of tube before feeding and that tubing	If the resident is able to be interviewed, suggested questions may be: Do you feel comfortable/safe with all the staff who perform the feeding?	Tube Feeding Review: - Plan of care - Must document tube placement and formula potency prior to each feeding.	- Has the feeding been ordered by a physician? - Is tube feeding nutritionally adequate? - Have attempts been made to discontinue tube feeding if indicated?	Nursing Services 405.1124(d)(f) 442.338(a)(2) Meal Service 442.331(c)

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Tube Feedings F133 (cont'd)	is irrigated before and after addition of medication. - The tube is clean and formula flows freely. - The equipment is clean and protected. If dressings are ordered, they are in place, clean, and dry. - The nasal tube is securely but comfortably secured on the face with skin maintained intact and without irritation. - The skin around the gastrostomy is kept clean and free from irritation or infection. It should be checked carefully for leakage of gastric contents. - A resident who has a N/G tube for a prolonged period of time should be observed for possible complications, such as nasal erosion, sinusitis, esophagitis, gastric ulceration, and pulmonary infection. - Resident is fed slowly with head elevated to 45° during feeding and at least 1 hour post-feeding.	If not, what happens? Are you losing or gaining weight? What is your goal? Ask Staff: - Please describe how you would carry out a resident's tube feeding.	- In the case of continuous feeding, tube placement must be documented at least every 4 hours. - Naso gastric tube must be secured in a manner that avoids creating pressure on the nose and nasopharynx. - Identify frequency, amt. of feeding based on the physician's order and time span over which each feeding is accomplished. - Medication and treatment records. - Fluid intake records. - Number of calories as well as amount of additional water. - Documentation present regarding removal and reinsertion of tubes. - Record should indicate measures taken to prevent diarrhea and constipation and to treat if they have developed.	- Is skin free from irritation; mouth care is given several times daily? (More frequent mouth care in the case of continuous feeding.) - Have changes in resident condition been noted and addressed (weight loss, constipation, diarrhea, skin condition)? - Have observed problems been coordinated with other departments and resolved? - Is feeding being monitored to ensure that feeding is occurring at the ordered/appropriate rate? - Varied supplements as preferences allow?	Dietetic Services 405.1125(c)

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Tube Feedings F133 (cont'd)	- Supplies for mouth care are in evidence, observe if possible for technique; mouth shows evidence of good care (i.e., moist, clean.)				
Nursing Services F137 **SNF (405.1124)** **ICF (442.338)** **B. Twenty-four hour nursing.** F137 **1. Assigned duties consistent with their education and experience/ based on the characteristics of the resident load.** F138 **2. Weekly time schedules are maintained.** F139 3. There is a sufficient number of nursing staff	Are personnel performing duties that are allowed under the State Nurse Practice Act? Do you observe care being rendered in an appropriate, competent manner? Does the time schedule posted indicate that at least the minimum required personnel are scheduled and actually on duty? What is the usual response time before a call bell is answered? In SNF's is an RN on duty during the day? Are licensed staff and aide staff functioning in appropriate roles? Where are staff spending their time?	Ask Resident: - Do residents generally feel that people taking care of them know what they are doing? - If no, explain. - Are your treatments done in a consistent manner? - If no, explain. - Do you feel that there are enough people here to take care of you? - If no, explain. - How long do you usually wait for help when you put your call light on? - Is there anything that doesn't get done as often as it should? Ask Staff: - Do you feel qualified to do all the work you are assigned to do? - If no, explain. - Do you feel you have enough training to keep up with the care the residents require?	- Review progress notes to determine who is giving care. - Review care plan to determine who the facility has assigned to care responsibility to. - Check staffing sheets for minimal requirements and time and attendance for actual staffing. - Review charts maintained for ADL medications, I & O, restraints, etc., to assure that sufficient staff are available for carrying out responsibilities as specified in patient care plans.	All nursing personnel must function within their State Nursing Practice Act. Levels of staffing meet at least minimum requirements. Nursing care needs must be identified by the facility & documentation, resident and staff interviews should determine if these needs are met. All nursing staff should have education or training to prepare them for the care they perform.	Patient Rights 405.1121(k)(g) Patient Care Policies 405.1121(l) Medical Records 405.1132(c) 442.318(a)(c) Patient Care Management 405.1124(d) 442.341 Staff Development 405.1121(h) 442.314

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F139 (cont'd) available to meet the total needs of all residents.	Check for staff who are actually on duty.	- If no, what else do you need?			
F140 4. There is a registered nurse on the day tour of duty 7 days a week (for SNF only). Intent. That all residents are cared for by personnel qualified to provide the care & that sufficient numbers & classifications of personnel are available.					

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Patient Care Management F167 SNF 405.1124(d) F168 ICF 442.341 F169 A. Each resident's needs are addressed in a written plan of care which demonstrates that the plans of all services are integrated, consonant with the physician's plan of medical care, and is implemented shortly after admission. F170 B. Each professional service identifies needs,	Observe resident level of physical, mental, emotional and social functioning. Note problems, potential problems, needs, using observation/interview/record review work sheet.	Ask Resident: - Are you aware that you have a plan of care? - Did you participate in developing a plan of care? - Do you/your family know what the plan is and details? (e.g., diet, ambulation, dressing, etc.) - Do you attend and participate in plan of care meetings? - Who else attends the plan of care meetings? - When did you last attend the meeting for your plan of care? - Does the staff assist you in achieving the goals on the plan of care? If not, who does or why not? - Do you have all necessary assistive devices and equipment? - Is there anything that is not part of your plan of care that you think should be included? - What happens if you question any treatment or procedure? Can you give an example?	Review: - Plan of care The content of the plan of care is of primary importance rather than the format. Separate care plans are not required for each discipline, but may be accepted if there is evidence that the various disciplines coordinate their planning. - Nursing assessment/reassessments and notes. - Physician orders. - Physician notes. - Assessments/evaluations and progress notes from all professional disciplines as appropriate. - Medication and treatment records as applicable. - Lab reports, as applicable.	- Are all resident's needs/problems identified? - Is the plan developed to meet these needs? - Does the plan demonstrate an interdisciplinary approach, and include: + Goals stated in measurable/observable terms? + Approaches (staff action) to meet the resident action goals? + Responsible disciplines/staff responsible for approachs to assist resident in achieving goal/goals? + Is plan being reassessed and changed as needed to reflect current status? + Does plan of care accurately reflect information gained from observation, interview and record review?	Physician Services 405.1123 442.346 Medical Records 405.1132 442.318 Resident Rights 405.1121(k) 442.311 24 Hour Nursing Service 405.1124 442.338 Specialized Rehabilitation Services 405.1126 442.343 Training 405.1121(h) 442.314 Resident Rooms 405.1134(e) 442.325 442.326 Infection Control 405.1135 442.328 442.324

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F 170 (cont'd) goals, plans, and evaluates the effectiveness of interventions plus institutes changes in the plan of care in a timely manner. INTENT The intent is to assure that the facility identifies the resident's (with residents/family input if applicable) needs through the coordinated efforts of all disciplines.		Ask Staff: - What is your input into resident's plan of care? - What aspect of the resident plan of care are you carrying out? - What is this particular resident's plan of care? - How do you assist the resident in carrying out the plan of care? - Who attends the care planning meeting? - Is the plan of care useful to you in caring for the resident? - Is there anything the resident needs that is not addressed in the plan of care? - How often is it reassessed?			Social Services 405.1130 405.1130(a) 442.344(d) Activities 405.1131 442.345 Dietetic Services 442.1135 442.332

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Restorative Nursing Activities of Daily Living F171-176 SNF 405.1124(e) ICF 442.342 442.343(a)(c) INTENT To assist the resident to attain or maintain his/her maximum level of independence and function?	A. Observe residents in need of assistance. 1. Is needed assistance provided? 2. Is resident provided assistance and instruction, as appropriate, in all ADL's to increase his/her level of independence? 3. Does staff minimize pain/discomfort while assisting resident? 4. Is resident taught transfer techniques? 5. Is resident assisted to toilet in timely manner? 6. Resident personal equipment available & within reach? Glasses Hearing aids Dentures [Artificial larynx]	Ask Resident: - What assistance do you need with bathing and/or dressing? Who helps you? - Does the staff plan with you your dressing/bathing schedule? - Do the nursing and activities staff coordinate your schedule so that you have the opportunity to participate in favorite activities? - Are you able to dress/bathe at times convenient for you? - Are you bathed consistently? (i.e., on the day(s) scheduled does the bath get performed?) - Where are you bathed? (bed, shower, tub?) - Are there adequate clothes available for you to wear? - Do they come back from laundry in appropriate condition? - How do you get in and out of bed? - If staff assists you, do they seem to be able to do their job appropriately? Do you always feel safe when	Review: - Plan of care + Reflects assessment, goals, methods to reach goals, service providers, evaluation, and achievement. + Addresses restorative nursing assessment, program initiation, implementation and evaluation of the progress over a reasonable time period. Professional judgement determines the assessment of appropriate time frames. + Identifies planning for potential discharge for all residents to determine a disposition on home care or an alternate level of care. - Nursing Notes + Demonstrate evidence of assessment, intervention, response to treatments/teaching and their progress toward independence, a maintenance level or a deterioration. + Provide evidence of interdisciplinary conferences.	Are patient needs identified? Verify that the plan of care addresses resident needs and is implemented as scheduled and that all appropriate information is documented. If goals are not reached, has a reevaluation been performed and goals revised? Does restorative nursing assist the resident to acquire a higher level of independence? Is sufficient time allowed to resident for learning to increase his/her level of independence? Are assistive devices used regularly as per plan and are they in good repair? Is there an assessment, and if appropriate, a plan for each ADL that the resident needs to gain independece in? Maintenance goals should be noted as appropriate.	Physicians Services 405.1124(a)(b) Nursing Services 405.1124(a)(b)(c) 442.342 Dietetic Services 405.1125(a) 442.331(c) Activities 405.1131(a)(b) 442.345(a)(b) Specialized Rehab. Services 405.1126 442.343(e)(1)(2)

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F171-176 (cont'd) ADL's (cont'd)	Prosthetic devices (eg. braces, artificial extremities). Adaptive equipment (e.g., built-up spoon, reachers). Orthotic devices (eg. splints, AFO's). Restraints (eg. vest, waist, wrist, ankle, mitts, nets, geri-chairs). Grooming items (eg. comb, brush, shaver). Oral hygiene (eg. toothbrush, toothpaste, mouthwash, denture cup). Self-feeding devices. Assistive devices for special sensory loss needs (eg. communication boards, large print books, magnifiers, writing tablets, picture cards, talking books). Training/re-training Prosthetic management Stroke adapted ADL's Self-injections of medications Bowel/Bladder Self-feeding Self grooming Ambulation	being helped? - Are staff members encouraging you to do things for yourself? - Do you have any problems getting to the bathroom on time? - Do you have any problems with leakage when you sneeze, laugh or at any other particular time? - How does the staff help you with these problems? - Are they aware of the problems? - Do you bowels move regularly? - If not, what do you/staff do about this? Are you able to feed yourself? - Are you able to get to the dining room by yourself? If not, why? In that case, what does staff do about this? - How long have you been up today? - Do you usually lie down for a rest? - If you need help getting into or out of bed, is staff available to help you when you need it? - Where do you spend most of your time - in your chair, wheelchair or in bed?			

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F171-176 (cont'd)	Colostomy/Ileostomy Care Respiratory Care (oxygen inhalation) Speech Mobility Upper extremity dressing Lower extremity dressing Observe at mealtime whether staff encourages/guides residents in self-feeding or feeds the residents.	Does anyone move your arms or legs or help you with exercises? - Have your sleeping habits changed since you came to the nursing home? If yes, in what way? - Are you able to get help during the night if needed? + What kind of help is needed? + Is staff response timely? - Do you feel there are adequate care supplies at this facility? - If not, can you give me an example of why you feel this way? - Is your family involved in assisting you or if learning to help you? - Do you feel there is adequate staff at this facility? - If not, can you give me an example of why you feel this way? - Does staff assist and/or encourage activities (e.g., R.O.M., ambulation ADL, communication programs, feeding)? - How often does staff assist in activities? - Is there anything resident would like to do			

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F171-176 (cont'd)		for himself/herself that staff is doing? - Is resident comfortable (e.g. free from pain)? - Is your cane/walker/crutches comfortable for you to use? - Did anyone measure you so you have the right size cane/walker/crutches? - Did anyone show you the correct way to use your cane/walker/crutches? - If the facility arranged so that you can get around easily? Ask Activities Staff Do you provide information to nursing staff about time and place of activities, plus names of residents who are to attend or those who might be interested in attending? Chair-bound Resident Ask Resident: - Does he/she know why he/she is in a chair? - Is resident assisted to use bathroom? - Is resident comfortable? - Does he/she see therapist? (O.T., Speech, P.T.) and how often? - Does resident go to a			

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F171-176 (cont'd)		therapy area or does therapist come to resident? - Is able to reach items needed? Ask Nurses Aide -Who give you information about the time and place of activities and which residents are to attend? How are you given this information? -How do you encourage a resident to do the most for themself? Wheelchair Resident Ask Resident: - Does he/she know why he/she needs a wheelchair? - Is resident trained and/or encouraged in independent W/C ambulation and activity? - Does resident know how to lock and unlock wheelchair? Ask Staff: - How is a resident set up for independent W/C ambulation? - Nurse Aide - has resident received instruction in transfer techniques? For Bed Bound Resident In addition to appropriate interview questions above:			

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F171-176 (cont'd)		Ask Resident: - How do you spend your day? - Can you do some things for yourself? - Does the staff give you a chance to learn self-care skills? Ask Nurse: - If the resident had access to a recliner chair, would he/she be able to be out of bed? - Is the time out of bed coordinated with the activity schedule and necessary care? Ask Nurses Aide: - Does this resident do any self-care? Why not? - If no, has anyone tried to teach him/her to do some care?			

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Positioning F175 SNF 405.1124(e) Intent To assure that the resident is positioned at all times to promote maximum therapeutic benefit and comfort, as well as safety.	Observe residents in bed, chairs, restrained, or in "protective devices" for - body alignment - positioning - contractures (when did they occur and what is being done)? - ROM program (observe extent & technique of provider) - Assistive devices (overhead pulleys, slings, splints, etc.) - Turning/repositioning schedule and adherence to the schedule. - Devices to maintain positioning, i.e., sandbags, extra pillows, etc. Specific Observations for the Bed Resident (as appropriate to condition). Positioning/body alignment Resting splints & correct application Foot positioning boards Trapeze Hand rolls Elbow/leg splints & correct application Restraints Siderails (padded) Special mattresses	Ask Resident: - How often are you turned/repositioned by the staff? - Is that often enough? - Are you comfortable now? Do you have any pain or discomfort? Where? - How long have you had joint stiffness (contractures)? - What kinds of exercise do you do every day, including range of motion (ROM)? How long does the exercise last and how frequently do you exercise each week? - Do you wear special devices? How often? - Consistently? - Are they always applied and removed appropriately and promptly? How Often? - By whom? Bed Rest Resident Ask Resident: - Why do you have to stay in bed? - How often does staff get you OOB? - Do they know how to get you up? - Who sets you up and/or assists you in bedside ADL's? - Does staff, therapist check positioning, supportive devices?	- MD orders for non-nsq interventions/treatments. - Plan of care should include at a minimum: + Restorative goals + specific joints to be exercised + devices to be used in positioning + frequency of treatment or repositioning + resident teaching information + resident teaching information + services responsible for carrying out the procedures + time frames for reaching goals - Nursing progress notes indicate: + Plan has been implemented + Progress toward goals + Response to information from reevaluation - Look for actual turning/repositioning schedule	Plan of care should be complete (addressing resident positioning needs) and plan is implemented on a daily basis. Care givers are knowledgeable re plan content Residents are turned as scheduled. In good body alignment with proper assistive devices & equipment. Contractures are prevented and/or treated. Plan is reviewed, reevaluated and revised at least quarterly, but must be done as often as patient condition dictates. Ask aide assigned to demonstrate the hand holds he/she uses for ROM. If aide doesn't know, ROM is probably not being done. Do it "at bath time" is not sufficient.	Rehabilitative Services 405.1126(h) 442.343(c)(2) MD Orders Activities Resident Rights Nursing-Staffing Inservice Social Service Dietary

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F175 (cont'd)	Blankets/pillows Clean, smooth linen Clean, appropriate bed wear Turning schedules ROM schedule O.O.B. (as tolerated) Water available All adaptive devices are clean and in good repair. All assistive supportive devices are clean and in good repair. **Specific Observation for the OOB Resident in Chair** (geri-chair, lounge chair in room, as appropriate to condition) Arrangement of room facilitates residents optimal independence (e.g., independent eating, grooming, T.V., radio, water). Positioning/body alignment. Blankets/lap robe, pillows, foot stool. Hand rolls, splints. Clean, dry attire. Pressure relief device. Restraints, with release & activity schedule. Call bell available.	- When? - Does staff answer call bells propmtly? How soon? - Is resident able to reach items (e.g., water call bell, urinal, emesis basin, tissues)? - How much confidence do you have when the nurses are helping you transfer, or turn and so on? - Does resident go to therapy area or does therapist come to resident? Bed Rest Resident Ask Staff: - How often is position changed? - What activity is done at the time (e.g., R.O.M., toileting, OOB, grooming? - What can resident do independently? - Is equipment available? - Who maintains and cleans the equipment? - What is the schedule for this? - What training have you had to learn to position patients correctly?			

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F175 (cont'd)	Specific Observation for the Wheel Chair Resident (as appropriate to condition, including deliberate alterations made to equipment for specific reasons.) - Proper fit - Good working condition - Appropriate arm rest, footrest, leg support, lap tray - Proper positioning - Pressure relief aids, (e.g., gel flotation pads, egg crate mattress, sheepskin) - Set up for independent W/C ambulation - Functional adapted toilet area - Transfer techniques Observe how staff wheel the resident (e.g., do they inform before starting movement)? Are patients moved wheeling forward and facing elevator doors? Observe staff for: - verbal cues - physical support - body mechanics Specific Observation for the Ambulatory Resident (as appropriate to condition) - Gait (steady/unsteady) - Appropriate devices for	- Was there any part of your orientation when you first came to work here that addressed positioning? - Do you have any periodic reviews/updates on positioning? Chair Bound Resident Ask Staff: - How often is resident repositioned/taken out of chair? - What is the activity at time of repositioning and/or release of the restraint? - What can resident do independently? Ambulatory Resident Ask Staff: Is resident encouraged to independently ambulate to and from activities and dining room (with or without personal assistance)? - Does resident do as much as he/she can independently? - What does resident do? - How do you know that resident is maximally independent? - If it is not working independently, how do			

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F175 (cont'd)	ambulation (e.g., cane, crutches, hemi-sling - Posture - Appropriate staff assistance in ambulation - Grab bars (halls, bath/shower area) - Functionally adapted toilet area	you deal with it? - Is there something resident would like to do that he/she is not allowed to do (e g., shave self, apply make-up, style own hair)? - What training have you had in learning to position residents and do range of motion? - What opportunity do you have for ongoing training? - Who does the actual training? Check question placement under Interviewing. May be more appropriate for resident's rights section. Observe wheeling technique used by staff.			
Nursing Services G. Administration of Drugs F183-184 SNF 405.1124(g) ICF 442.337 F186 1. The patient is identified prior to administration of a drug.	Observe a drug pass with at least 20 residents receiving medication. See SOM Appendix N. Transmittal No. 174 for details of the Surveyor Methodology for Detecting Medication Errors. - Observe medication administration techniques (e.g., hand-	Ask Resident - Do you always receive your medication on time? - If not, what is the problem? - Do you receive the correct medication? - What does it look like? - Who explained your medications to you? - What reactions do you have? - What happens if you have a question or refuse to take your medication? - Who gives you your medication? - Do your medications change in appearance?	Review the medication administration record. (as appropriate) See S.O.M. Appendix N. Transmittal No. 174 for details of the record review.	If the combined total of significant & non-significant errors is 5% or above, a deficiency is present. Any significant error is cause for a deficiency. See Appendix N for details.	Physician Services 405.1124(b)(7) Pharmaceutical Services Supervision 405.1127(a) 442.336(a)(b)

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F187 2. Drugs and biologicals are administered as soon after doses are prepared.	washing, pouring of dosage, position of resident).	- Do the nurses stay with you when you take your medication? - Do any of the medications bother you? Ask Staff: - Do you generally have available the medications you need? - Are there any problems in administering medications? Note drug doses refused by resident and how handled by staff.			
F188 b. Administered by same person who prepared the doses for administration except under single unit dose packet distribution system. Exception: ICF residents may self administer medications with their physician's permission.					

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H. Conformance with Physician Drug Orders F189 F190 F191 SNF 405.1124(h) ICF 442.334(a) Drugs are administered in accordance with written orders of the attending physician. Intent All residents receive medications as ordered by the physician.	Combine with observation of drug pass.		- Review the latest recap of the physicians orders - Review the medication administration record (as appropriate) - See S.O.M. Appendix N, Transmittal No. 174 for details of the record review.	See Appendix N for details	Physician Services 405.1123(b)(7)

SURVEY AREA CROSS REFERENCE	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	
DIETETIC SERVICES (Condition of Participation) F193 SNF (405.1125) A. Menus and Nutritional Adequacy F194 SNF (405.1125(b)) F194 ICF 442.332(a)(1) F196 Menus are planned and followed to meet the nutritional needs of each resident in accordance with physicians' orders and, to the extent medically possible, based on the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences.	o Specific Observations which might be indicative of possible nutrition problems: Clinical - underweight/ overweight - dehydration - edema - cracked lips - pallor - dull or dry hair - swollen or red tongue - bleeding gums - decubitus ulcers - infections o Physiologic factors which may affect intake: - Swallowing difficulties - Vomiting - Food intolerance - Poor dentition - Sore mouth - Constipation - Diarrhea - Inability to feed slef - Decreased visual and olfactory acuity - Unable to communicate - Loss of appetite o Psychological/Social - Confusion	Ask dietary manager to explain the procedure for making substitutions and recording the changes. - Is menu usually followed? Ask Resident: 1. How are your meals? 2. Are there foods you are not allowed to have? 3. Are you on a special diet? 4. Do you receive foods that are not appropriate for your diet? If so, what do you and the staff do about that? 5. What time do you receive breakfast, lunch and supper? Do you always receive a meal at mealtime? If not, why? What happens then? 6. Do you like the taste of the food? 7. Is the temperature appropriate (i.e., milk chilled, coffee hot, etc.)? 8. Do you get enough to eat? What do you do if you're still hungry after a meal?	Review Nutrition assessment for the following documentation: o Usual/ideal body weight/ height o Dietary allergies/ sensitivities, ability to chew and swallow regular foods without difficulty. o Full or partial dentures o Mental and emotional condition o Physical appearance, skin condition o Appetite and food preference. o Vitamin and mineral supplements. o Food and fluid intake in measurable terms and frequency of meals. o Degree of assistance needed in eating, related mobility, vision, or other identified problems. o Medications (e.g., diuretics, insulin, antibiotics, etc.) o Related laboratory findings (e.g., fasting blood sugar, cholesterol, sodium, potassium, hemoglobin, BUN, serum albumin, transferrin or creatinine-height index if available).	o Were physician diet orders followed? o Did nursing plan for feeding and assistance at mealtime? o Is there rehabilitative use of assistive devices, if appropriate? o Is modification of consistency of meals made if resident has a problem or change in condition? o Are between meal and bedtime snacks provided as needed? o Is socialization at meals provided? o Has dietitian provided counseling of resident and family as needed (related to diet)? o Usual body weight is maintained/supported? o Is there evidence that the plan is being carried out (e.g., documentation in the resident's chart, observation by the surveyor, and resident/staff interviews)? If the resident refuses meals or does not respond to intervention, the notes in the chart should indicate efforts to intervene or provide counseling.	Physician Services 405.1123 442.346 Medical Records 405.1132 442.318 Nursing Services 405.1124(e)(f) Specialized Rehabilitative Services 405.1126 Patient Care Management 405.1124(d)

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F196(cont'd) Intent Ensures that each resident receives food in the amount, kind, and consistency to support optimal nutritional status.	- Excessive food likes and dislikes - Refusal to eat o Selected biochemical changes which might indication changes in nutritional status: - Visceral protein status o serum albumin o transferrin o BUN o Serum electrolytes During mealtime observe the resident for: - adherence to food preferences - adequate space for eating - self-feeding skills - proper position for eating - ability to eat foods served - use of adaptive feeding devices - amount of food actually eaten - protection of resident's clothes - amount of time resident is allowed to chew and swallow - Assistance provided as needed to and from dining area - All beverages are covered]	9. Do you receive nourishment in the evening? Do you have a choice about what you want to eat? 10. Do you receive medicines during meals? If yes, do you know what it is or what it is for? 11. Do you get food from outside of facility that you buy or family brings? How often? What kind of food? 12. How often does anyone from the kitchen come to ascertain your feelings and opinions on the food service, your portion size, etc.? 13. Where do you eat (e.g., dining room, your room, etc.)? Is this your choice? Do you have a choice of where you eat? 14. How often have you seen a therapist for your swallowing difficulties?" "How has the therapist instructed you/staff/family on methods to improve your swallowing? Ask Dietician - Describe the meal planning input you receive from residents.	o Food/drug interactions o Mental/emotional assessment as it relates to resident's food habits. Review: o Plan of Care o Nursing Notes Review: o Physicians orders o Progress notes o Notes from other professional disciplines as appropriate. Nutritional status depends not only on adequacy of menu planning but also whether the resident eats the food and how the body uses it. While the surveyor is not responsible for individual nutritional assessments of residents, when specific information is needed during the survey to make a compliance decision, the surveyor will utilize the following minimum assessment guideline: Menu Evaluation o Adequate in energy and nutrients - Protein - Calories	Is there evidence that the resident's progress is regularly observed (e.g., awareness of food and fluid intake such as acceptance of foods, food consumed, and resident's appetite)? o Is fluid intake for resident encouraged, Foley catheter, problem feeders monitored? o Is there general evidence as to whether poor resident conditions are due to poor care or whether the facility has taken appropriate measures to prevent or resolve problems. o Is there indication of progress toward desired outcomes? If not, is the evidence of re-evaluation available within specified time frames? o When the antropometric and clinical data do not correlate with dietary data, (food intake, dietary supplements) the surveyor should take note that the problem may not be nutritional.	Nursing Services -405.1124(f)

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F196(cont'd)	Assistance being provided in case of choking, incontinence, falling, or other emergencies. Nursing Staff supervision of dining areas including residents' rooms during meal times.		- Vitamin C - Calcium Selected evaluation of residents for in depth review: A check list can be used to evaluate daily menus for basic foods: (use standard serving protions) Daily food plan should include: MILK GROUP 1 pt milk MEAT GROUP 5 equivalents:* 1 equivalent equals 1 oz. of meat (edible portion) weighed after cooking (this includes eggs, dried peas, beans, nuts, and all meat, fish and poultry). VEGETABLE AND FRUIT GROUP 5 services or more, including a dark green or deep yellow vegetable for vitamin A value every other day and a citrus fruit or other fruit rich in Vitamin C daily.		

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F196 (cont'd)	Observe serving portions sizes on all menu items: MILK GROUP - 1 pint daily Source of: Protein Calcium Phosphorus B Complex MEAT GROUP - 5 lean meat equivalents (1 meat equivalent = 1 oz meat, poultry, fish, cheese & eggs; also dried peas, beans, and nuts). Source of: Protein Iron Vitamin B12 VEGETABLE AND FRUIT GROUP - 5 servings or more (1/2 cup = 1 serving) Source of: Vitamin A,C, B6, Folacin, Fiber BREAD-CEREAL-POTATO-LEGUME-PASTA GROUP - 7 servings (1 serving = 1 slice bread; 1/2 cup other; 3/4 cup flake-type cereal).		BREAD-CEREAL-POTATO-LEGUME-PASTA GROUP 7 servings FATS AND SWEETS (Without this group the diet contains 1,415 Kcal) Diets should be adapted from facility's currently approved diet manual. Menus are dated and contain minimum portion sizes. Are substitutions noted on the file copy? Are substitutions made within the same food group i.e., meat for another source of protein in the meat group, or vegetable of similar nutritional value?		

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F196 (cont'd)	FATS AND SWEETS (to increase caloric intake) IODIZED SALT (unless contraindicated) Adequate fiber in diet		o Documentation of decision to withdraw or begin artificial feeding and hydration. Check menus for variety Are they specific (i.e., states kinds of fruit, juice, vegetable)? DIETARY SERVICES SELECTED NUTRITIONAL REQUIREMENT RECORD REVIEW N.B. The basal energy expenditure (BEE) and calorie requirement using Harris-Benedic formula recognizes the variation in energy needs for individuals. 1. Anthropometry- Weight/Height NOTE: The following sample formulas and guidelines are not the only acceptable guides available. The surveyor should ask to use the assessment guidelines used by the facility before using the ones provided here. o Important indicator of nutritional outcomes. o Disease state can have adverse effect on desired body weight.		

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F196 (cont'd)			2. Weight for Height Calculation Females: Allow 100 lbs. for first 5 ft. of height plus 5 lbs. for each additional inch Males: Allow 106 lbs. for first 5 ft. of height plus 6 lbs. for each additional inch Estimating Caloric Needs 1. FORMULA: Harris-Benedict Equation Men: 66 + (13.7 x Wt. in Kg) + (5 x Ht. in cm) – (6.8 x Age)=BEE Women: 65.5 + 9.6 X Wt. in Kg.) + (1.7 x Ht. in cm) – (4.7 x Age)=BEE Parenteral Anabolic: 1.75 x BEE Oral Anabolic: 1.5 x BEE (Kcals)		

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F196 (cont'd)			Oral Maintenance: 1.20 × BEE (Kcals) Metric Conversions (Approx) pounds (lb.) × 0.45 = kilograms (Kg) inches (in.) × 2.5 = centimeters (cm) Estimating Protein Needs 1. Allow 0.8 gram protein per kilogram of ideal body weight. 2. Increase to 1.2 - 1.5 gm/kg for patients with depleted protein stores (decubitus, draining wounds, fractures, etc.). Fluid Requirement Based on actual body weight: Over 55 years with no major cardiac or renal diseases: (NOTE: 2.2 lbs. equals 1 kg of body weight)		

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F196 (cont'd)			Example: 120 lbs/2.2 lbs. = 54.5 kg (55 kgs) 55 kg x 30 cc - 1,650 cc/day Note: Isotonic Standard Tube Feeding = Approximately 80% water. Amputation % of Body Weight Leg 20% Below Knees 10% Arm 6% At Elbow 3.6% Suggested Standards for Evaluating Significance of Weight Loss % of body weight loss Interval / Significant Loss / Severe Loss 1 week 1-2% 2% 1 month 5% 5% 3 months 7 1/2% 7 1/2% 6 months 10% 10% From Blackburn, et al: "Nutritional and Metabolic Assessment of the Hospitalized Patient: JPEN vol. 1, 1977.		

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F196 (cont'd)			Lab Indices for Visceral Proteins		

	Mild Deficiency	Moderate Deficiency	Severe Deficiency
Albumin g/dl	3.5-3.2	3.2-2.8	2.8
Total Lumphocyte Count (cu/mm)	1800-1500	1500-900	900
Transferrin (If Available)	200-180	180-160	160

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
B. Therapeutic Diets F197 SNF 405.1125(c) F198 ICF 442.332(b)(1)(2)	System for the provision of diets: o Dietetic service Kardex or file o Therapeutic menus o Nourishment preparation and service o Adequacy of nourishment o Individual menus or diet cards	Ask Staff: o Number, type of therapeutic diets? o Time of nourishment activity, who's responsible? o Nourishment provided for day of survey?	Review: - Physician diet orders in medical record - Nurses' Kardex - Dietary Kardex - Therapeutic diet menu - Diet cards Note: - Consider appropriateness of special diet-updated and reviewed since admission. - Progress notes reflect reevaluation of resident's progress on diet.		**Nursing Services** 405.1124 405.1124(c) (d.) Patient care plan (f.) Supervision of patient nutrition
F199 1. Therapeutic diets are prescribed by the attending physician. F182 2. Therapeutic menus are planned in writing, prepared, and served as ordered with supervision from the dietician and advice from the attending physician whenever necessary.	SPECIAL FEEDINGS: The surveyor should also attempt to observe that: o Staff use proper technique in administering feedings and medications. Check to see that staff checks for location of tube before feeding and that tubing is irrigated before and after addition of medication. o Unused milk-based tube feeding should be discarded in a timely manner	The surveyor should interview staff regarding their knowledge of the feeding schedule and training in administering tube feedings. Some residents having difficulty in speaking or swallowing with the tube in place (i.e., poor toleration). The surveyor should inquire if mouth feeding was attempted. Ask Resident: If the resident is able to be interviewed, suggested questions may be: 1. How long have you been fed by this tube? 2. When was the last time you tried to eat by mouth? What happened? 3. How often do you receive the feeding? Is this consistent?	Selected number of residents on therapeutic diets should be considered for indepth reviews. Tube Feeding Review: - Plan of Care - Identify frequency, amt. of feeding based on the physician's order and the time span over which each feeding is accomplished. - Medication and treatment records - Fluid intake records - Number of calories as	On Pureed diets: o Ordered by physician o Prepared fresh daily o Same calories and/or food groups as if served whole. Pureed foods are coordinated with general/regular menu. On Tube Feeding: o Has the feeding been ordered by physician? o Is tube feeding nutritionally adequate? o Have attempts been made to progress tube feeding if indicated? o Have changes in resident condition been noted and addressed.	

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F197-199 (cont'd)		4. Does the staff help you in feeding? Do you feel comfortable/safe with all the staff who perform the feeding? If not, what happens? 5. Are you losing or gaining weight? What is your goal? 6. How often is the tube changed? Who does this? Do you feel comfortable/safe with all staff who perform this procedure?	well as amount of additional water - Periodic reassessment of ability to swallow - Record should indicate measures taken to prevent diarrhea and constipation and to treat if they have developed.	weight loss, constipation, diarrhea, skin condition)? o Have observed problems been coordinated with other departments and resolved? o Is feeding being monitored to ensure that feeding is occurring at the ordered/appropriate rate? o Varied nourishments as preferences allow?	
		Interview staff regarding knowledge of diabetic diets. o What nourishment does the diabetic patient receive? o If diabetic patient refuses the meal, what is done to supplement the meal? If resident is able to be interviewed, suggested questions: 1. How long have you been on your diabetic diet? 2. Do your know some of foods you must avoid? What are they?	Diabetic Diets Review: o Pertinent Laboratory data: - urinary glucose - serum glucose o Wt. gain/losses	On Diabetic Diets and Other Therapeutic Diets o Ordered by Physician o Varied, nutritionally adequate o Individualized to suit resident o Re-evaluation indicates diet meets objectives. If not appropriate, documentation is provided o Laboratory results support diagnosis o Between meals nourishment provided as needed and recorded in measurable amounts.	

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F197-199 (cont'd) F198 Therapeutic diets prescribed by the attending physician	Observe tray/meal service: o Low sodium diets are platable (taste) o Sugar sources on diabetic diet trays o Salt sources on sodium restricted diet trays.	3. Do you receive a nourishment between meals or before going go bed?			
		FOR THE RESIDENT WITH DECUBITUS ULCERS			
F199 Therapeutic menus are planned in writing, prepared and served as ordered with supervision from the dietician and advice from the physician whenever necessary.	Functioning system to provide the needed nutrients: - Resident's general appearance - Meal service + Food acceptance + Adherence to food preferences - Food supplement + Type to support + Method of service + Assistance provided + Timely provision as ordered - Portion sizes - Conforms to physicians orders	Ask Staff: 1. Regarding knowledge of dietary needs. 2. What do you do when this resident refuses milk, meats, bread, etc.? 3. What nourishments are provided to this resident? How often? 4. What happens when a weight loss is noticed with this resident? Ask Resident: 1. Has anyone talked with you about the importance of eating your meals? 2. Do you get foods that you don't eat on your tray? 3. When do you feel hungry? 4. Do you get between meal nourishments?	1. Identify residents with conditions that immobilize or prevent voluntary body movement. 2. Identify location, number, size and depth of decubitus ulcers. 3. Calculations of kilocaloric and protein levels as needed. 4. Micronutrient need assessment and recommendation. 5. Progress notes + monitor weight + monitor healing of decubitus ulcers. 6. Pertinent Laboratory Data + Hemoglobin/Hematocrit + Serum Albumin + Total Lymphocyte Count 7. Fluid Intake + sufficient to maintain hydration	A system is in place to provide the type and amount of nutritional support needed by the residents who have developed decubitus ulcers. Food and supplementation are provided in a method to ensure intake of nutrients needed by residents with decubitus ulcers. Nutritional intervention is assessed and reassessed to ensure appropriate intervention for acceptable health care outcome.	Nursing Service 405.1124 (d) Patient Care Plan (f) Supervision of Patient Nutrition

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F197-199 (cont'd) F198 **Therapeutic diets prescribed by the attending physician** F199 **Therapeutic menus are planned in writing, prepared and served as ordered with supervision from the dietician and advice from the physician whenever necessary.**	**RENAL REVIEW** **System in place for the the correct provision of renal diets.** **- Individualized menu** **- Dietary Staff** **Utilize menu when serving diets.**	Interview Staff regarding **knowledge of renal diets:** 1. What foods should be restricted when a patient has kidney problems? 2. What nourishments are given to these patients? 3. Are fluids restricted? Ask Resident: 1. Are you on a special diet? 2. What foods must you avoid? 3. Do you feel hungry? 4. Do you eat everything at mealtimes? 5. Are the foods the kitchen sends you the correct ones for your diet? 6. Has the dietitian explained your diet to you?	Renal Patient Diet Review - Pertinent Laboratory Data + Serum Sodium + BUN + Serum Potassium + Albumin + Hematocrit + Creatinine - Pertinent Medications + Vitamin/Mineral + Supplements - Weight gains/losses	On Renal Diets **- Ordered by physician** **- Written menu nutritionally complete in so far as medically possible, including calories** **- Individualized to suit resident** **- Laboratory testing as needed** **- Coordination with dialysis unit to determine effectiveness of diet**	**Nursing Service** 405.1124 (d) Patient Care Plan (f) Supervision of Patient Nutrition

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
C. Preparation F204 SNF 405.1125(e)	Observe: o Feeding assistance is provided or not provided by staff o Length of time residents sit and wait for meal service o Food is served soon after cooking or refrigerated o Trays are free of spillage of foods or liquids o Foods are appropriately covered and kept at a proper temperature o Cooking and service utensils are clean, sanitary and greaseless o Refrigerated foods must be covered o Leftover and pre-cooked foods must be dated and labeled o All cooked food stored above raw meats in refrigerator o Temperature gauge on or in refrigerator to record temperature o Shelving to allow air circulation o Food not stored in refrigerator must be stored off the floor (This is applicable to food stored in walk-in refrigerator and freezer.)		Review: o Plan of Care o Progress notes o Notes from other professional disciplines to determine rehabilitation potential to self feed, use of assistance devices. o Record of food substitution to determine alternate choice provided o Standardized recipes	The facility has kitchen and dietetic service areas adequate to meet the food service needs. These areas are properly ventilated, arranged, and equipped for sanitary refrigeration, storage, and preparation of food. Equipment and storage areas are clean, well maintained, within proper temperatures ranges, and safe Proper temperatures: (Fahrenheit) Frozen food storage — 0 or below Cold food storage — 40–45 degrees Hot food holding equipment — 140 degrees minimum Dishwasher wash cycle — 150 - 160 degrees Dishwasher rinse cycle — 160–180 degrees or a color change in thermo-paper; or adherence to manufacturers recommendations	
F205 1. Food is prepared by methods that conserve its nutritive value and flavor.					
F206 2. Meals are palatable, served at proper temperatures. They are cut, ground, chopped, pureed or in a form which meets individual resident needs.					
F207 3. If a resident refuses food served, appropriate substitutes of similar nutritive value are offered.					

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F207 (Cont'd) INTENT To provide foods that are safe and nutritious SNF 495.1125(e)	- No rust on shelves - No dripping or spillage on shelves and floors - Degree to which diet modification is commensurate with residents tolerance and capability - Residents for meal satisfaction - Observe appearance of food color, texture, aroma, and flavor - Less than 75% of meal is consumed - Type of substitutions provided		- Progress notes - Diet card - Day's menu substitute record	Dietary personnel are clean and free of infectious disease. They practice acceptable techniques and procedures to keep foods at proper temperatures and protected against contamination. Is dietary information pertinent to dietary modification? Has resident been assessed for eating program to maintain independence? The food substitute is of similar nutritive value as the refused item (e.g., milk refused, alternate of calcium rich food should be provided.	

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
D. Frequency F208 SNF 405.1124(d)	o Menus as under A on page 63 o Who serves nourishments o Nourishment list and schedule	Interview various residents about the nourishment service: o Are nourishments offered routinely? o At what time are they offered? o By whom? o What kind of nourishments are offered?	Review o Menu as under A o Nourishment List	Three meals or their equivalent are served daily with not more than a 14-hour span between the evening meal and breakfast. The nourishment service is more difficult to evaluate: must find evidence that patients are offered nourishments on a planned basis and documented.	
F209 ICF 442.331(a)					
F210 1. At least three meals are served daily at regular hours with not more than a 14-hour span between a substantial evening meal and breakfast.					
F211 2. To the extent medically possible, bedtime nourishments are offered to all residents					

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
E. Staffing F212 SNF 405.1125 (a)	- Food service personnel are on duty for all defined dictary responsibilities: - Supervision - **Food Preparation** - **Dishwashing** - **Cleaning** - **Duty Schedules**	- Interview personnel to verify that they are aware of their responsibilities and job descriptions.		- From an assessment of the total dietetic service operation: + The dietetic supervisor is capable of the overall management and supervision of the dietetic service. + There are dietetic personnel on duty over a 12-hour period who demonstrate ability to perform tasks adequately. + Dietetic personnel receive appropriate orientation and training consistent with their duties and responsibilities. There is evidence that the dietetic staff are knowledgeable about food service policies and procedures and apply these accepted professionals practices in their daily work. + Services provided are consistent with the size, scope and facilities available.	
F213 1. Food service personnel are on duty daily over a period of 12 or more hours. Intent Persons are providing services commensurate with their level of training; and at the level of sophistication needed by the residents.					

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
SPECIALIZED REHABILITATIVE SERVICES F214 SNF 405.1126 F215 SNF 405.1126(b) F216 ICF 442.343 A. PLAN OF CARE ICF442.343(e)(1)(2) F217 Rehabilitative services are provided under a written plan of care, initiated by the attending physician and developed in consultation with appropriate therapist(s) and the nursing service. B. THERAPY F218 ICF442.343(a)(c)(d) Therapy is provided according to orders of the attending physican in accordance with accepted	OBSERVE RESIDENTS As per "Restorative Nursing Activities of Daily Living" SNF 405.1124(e)2(b) ALSO: OBSERVE RESIDENTS IN THERAPY AREAS: - Is privacy provided during treatment, as applicable (e.g., cubicle curtains, room dividers, one to one area)? - Is there appropriate, courteous resident/staff interaction? - Are therapy areas appro-priate to treatment given (e.g., small, quiet area for speech/ language/ hearing test and sessions, large for P.T., exercise and therapy groups, O.T. perceptual testing/splinting, A.D.L. adaptations area, as applicable)? - Is equipment clean and in good working condition? Is it operating as per manufacturer instructions (e.g., hydrocollator temp., parafin, whirlpool, etc.)?	ASK RESIDENT: (or ask staff, if resident has severe communication problem): - Are you receiving any kind of therapy? P.T.? O.P.? Speech? - What kinds of therapist(s) are working with you on your swallowing problem? - What kinds of therapists have instructed you on how to improve your swallowing? - How do the methods to improve swallowing help you? - How often do you see the therapist? - What happens if the therapist is absent for scheduled treatments? - Where do you receive your therapy? - How long have you been receiving therapy? - Do other staff members assist with therapy? Who and in what way? - Are you in a comfortable environment (room temperature, privacy, etc.)? - Do you have input into developing or revising your therapy treatments? -What things did you do immediately before entering this facility, that you are unable to do now? ASK THERAPY STAFF: - How many days/hours per week do you provide therapy? - Do you participate in the development of the res-	REVIEW: - Plan of care - Doctors' orders - Nursing assessment and progress notes - Aide assignment sheets - Therapy assessments/ evaluations (includes a minimum of): + name, age, date, diagnoses + referring physician and reason for referral + history, precautions, limitations + objective documentation (e.g., tests, measurements) + rehabilitation potential - Treatment plan (includes a minimum of): + specific rehabilitation needs and objectives + treatment to meet specific measureable rehabilitative goals + Type, amount, frequency, duration, modalities + name of therapist(s) who will provide treatment + restorative nursing follow-thru (recommendations for plan of care)	- Are rehabilitation services integrated with restorative nursing? - Do therapists participate in development of resident plan of care? - Do observations and interview indicate that services are provided in conjunction with 24 hour nursing, and in accordance with the overall plan of care regarding restorative nursing and specialized rehabilitation services?	Nursing Services 405.1124 442.338 442.319 442.341 Physician Services 405.1123 442.346 Medical Records 405.1132 442.318 Activities Program 405.1131 442.345 Resident Rights 405.1121(k) 442.311 Training 405.1121(h) 442.311 Infection Control 405.1135 442.315 442.327 442.328

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F218 (cont'd) professional practices by qualified therapists or qualified assistants. C. PROGRESS ICF 442.343(f)	- Are assistive devices being provided as needed? - Do assistive devices fit well, function and are used properly (e.g., wheelchairs, crutches, braces, glasses, hearing aids, canes, artificial limbs assistive eating devices)? - Is staff responsive to resident expressions of discomfort? - How are the prescribed treatments and training meeting the needs of the resident? - Are parallel bars sturdy and well secured to floor? Are systems designed for weight lifting sturdy and well secured; if attached to wall with rigging and hand grips in good conditions? - Are nonverbal residents provided with means of communication (e.g., writing tablets and utensils, picture cards)? - Are visually impaired residents provided with	"aides" In what way (if interviewing the registered physical therapist)? - How do you assure carry-over of therapeutics in your absence? - How often do you provide inservice to staff? What topics are covered? - Do you have opportunities to attend inservices? - How do you communicate patient progress/regression, etc. with physician, nursing personnel, family, other disciplines? - How many residents currently are receiving P.T., O.T., Speech-language pathology and audiology therapy (SLP/AI) . - Do you utilize the services of a certified occupational/therapy assistant (if interviewing the registered occupational therapist)? If so, in what way? - Is space available for the conduction of your therapy? - Is equipment readily available to meet resident needs? - Is there a coordinated interdisciplinary	+ identifies modalities that will be delegated to non-skill staff - Progress notes indicate that plan of rehabilitation care has been re-evaluated by the physician and therapist as necessary but at least every 30 days. - Communication with physician: + 2 week progress after initiation + monthly progress + discharge summary - Treatment documentation: + frequency + summary		Physical Environment 405.1134 442.324 442.325 442.326 442.328 442.329 442.330 Dietetic Services 405.1125(e) 442.329 442.331(c)
F219 1. A report of the resident's progress is communicated to the attending physician within 2 weeks of the initiation of specialized rehabilitative services. EXCEPTION: ICf resident's progress must be reviewed regularly.					

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
	magnifiers and large print books? - Is equipment such as whirlpool cleaned between patients?	approach toward rehabilitation of the geriatric resident evident in your facility? In what way do you see this?			
F220 2. The resident's progress is thereafter reviewed regularly and the plan of rehabilitative care is re-evaluated as necessary, But at least every 30 days by the physician and therapist.					
EXCEPTION ICF resident's plan must be revised as necessary INTENT Therapy services are provided that will assist the resident to attain his/her optimal level of function.					

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Pharmaceutical Services F221 SNF 405.1127	- Observe residents for excess sedation or adverse effects: + drooling + shuffling gait + involuntary movements of limbs, tongue, facial muscles + loss of affect + drowsiness + postural abnormalities + pill rolling movement - Observe for depression aggitation	Ask Resident: - Are you aware of the medications you are taking--use, frequency, contraindictions? - Has your physician discussed the medications you are taking, with you? - How many medications are you taking? - How do you feel the medication helps you? - How do medications bother you? (e.g., make you feel nauseated or dizzy) - Have you told anyone about this? Ask Staff: - How often does the pharmacist review the resident's medications? - To whom does he report any irregularities? - When the pharmacist reports irregularities, what is done about it? - To whom do you report any problems about medication? - Do you feel the residents are receiving the proper medications, amount and kind? - Is the pharmacist available to you for consultation?	Review medical record: - to see if pharmacist or nurse has reviewed a drug regimen on a monthly basis. - for evidence that the reviewer has reported irregularities to the physician or other who has authority to correct the irregularities for evidence that the irregularities have been evaluated. - review nurses notes, progress notes, care plan, etc. for any adverse reaction to medication and indication that corrective action was taken. - screen the drug therapy of the residents included in the sample using the indicators (forms if prepared) outlined in SOM Appendix N Transmittal #174. - review pharmacists drug regimen monthly reports to determine if pharmacist has commented on potential irregularities, screened out through this process (need full year).	Reviews were performed in the facility. There was evidence of a review performed on every resident whose record was reviewed indepth. In records reviewed, the average prescription utilization was not substantially over 6.1 If it is, review for appropriateness. Apparent irregularities were identified and reported. * Refer to SOM Appendix N in 174 for further information on drug regimen review.	Physicians Services 405.1123(b) 442.346 Nursing Services 405.1124 442.338
F222 A. Supervision					
F223 ICF 442.336(a)(b)					
F224 SNF 405.1127(a) The pharmacist reviews the drug regimen of each resident at least monthly & reports any irregularities to the medical director and administrator.					
A registered nurse may be utilized to perform this monthly review for ICF residents. Also the attending or staff physician must review medication quarterly.					

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F224 (cont'd)		- Where does the pharmacist perform his drug regimen review?			
B. Labeling of Drugs and Biologicals F225 SNF 405.1127(c) F226 ICF 442.333 F227 The labeling of drugs and biologicals is based on currently accepted professional principles and includes the appropriate accessory and cautionary instructions as well as an expiration date when applicable. INTENT To assure that residents receive medications as ordered and that they are monitored for possible side effects.	Observe labels of medications for residents observed on drug pass tour for: - name of drug - dosage form - strength of drug - quantity of drug - expiration date - presence of a control number - appropriate accessory or cautionary statement				

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Laboratory and Radiological Services F228 SNF 405.1128 F229 SNF 405.1128 (a) A. Provision of Services F230 1. All services are provided only on the orders of a physician. F231 2. The attending physician is notified promptly of findings.	Observe symptoms of targeted residents, e.g., drainage, odors, jaundice, fevers, edema, etc.	Ask Nursing/Rehabilitative Staff: - What do you do when you think a resident needs laboratory work done - blood work, cultures, etc.? - How long does it take to get lab results back? - What do you do with the results when they do come back? - Do you have any problems with your laboratory services? - How are lab specimens stored? - Do you have any instruction from the lab regarding collection and storage of specimens?	Review the physician's order sheet to see if: - orders for lab services are signed - that there are orders for tests that have been done. Nursing progress notes are reviewed for documentation of physician notification of lab results. Physician progress notes or other documentation indicating that the physician is aware of lab results. There are lab reports on the medical record for all tests ordered (except if just performed).	There must be signed physician orders for all lab/radiology services performed. Record results of all testing in the medical record. There is documentation in nursing or physician notes to indicate the results of lab tests were promptly communicated to the physician. When lab tests are performed the resident should be informed of significant findings and the possible therapeutic alternatives.	Nursing Services 405.1124(a)(b)(c) 442.343 Physician Services 405.1123(b)

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F232 3. Signed and dated reports of a clinical laboratory, x-ray and other diagnostic services are filled with the patient's medical record. INTENT To assure that lab tests are performed as ordered and findings are reported to physicians are made aware of symptoms that may require lab tests.					

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Social Services F233 SNF 405.1130 F234 SNF 405.1130(a) F235 ICF 442.344(d) A. Plan F236 The medically related social and emotional needs of the residents are identified. B. Provision of Services F237 1. Services are provided to meet the social and emotional needs by the facility or by referral to an appropriate social agency.	Observe resident for: - level of alertness - behavior exhibited (disoriented, confused, uncooperative, disruptive, aggressive, anxious, withdrawn, isolated, lonely). - personal appearance - apparent disabilities - apparent vision and/or hearing problems they exhibit as you talk to them - interaction to staff, other residents, family, visitors - participation in group activities - independence in activities, decision making - Therapeutic staff intervention: constructive reaction to resident's behavior - resident's participation on policy making bodies and committees of facility, e.g., resident councils.	- How long have you been in the facility? - Can you explain to me why you are here? - Have you had any problem adjusting to the facility i.e., loss of independence? - Have you had any other problems? - Has staff been helpful, e.g., financial? - Do you have any family or any other visitors? - Do they have any problems with which this facility has not been helpful? - If exhibiting disruptive depressed, agitated, anxious, etc. behavior- I noticed that you are upset (quiet, nervous, unhappy) today, Can you tell me what has bothered you? - Does staff respond to your suggestions about your own care? - Did you participate in planning what care you will get and who will give it to you? - Do you make use of the dining, activity, community room, and/or outdoor area?	Review medical records of residents selected for in-depth review to determine that: - Assessment and plan of care identifies residents medically related social and emotional needs and/or problems. - Resident's family and home situation, information related to medical and nursing requirements, and community resources are considered in making decisions regarding the residents care. - Medical records contain current specific information signed and dated which highlights the social and emotional needs of the resident and significant findings and actions are entered promptly in the medical record. - Social service notes address the following, if applicable: + losses due to aging + relationship with staff and other residents + mental status + behavior problems + adjustment to the facility + illness	The residents social and emotional needs are identified. The plan of care addresses those needs. The plan of care is being followed, reviewed and revised as necessary. The family's needs and concerns are addressed if applicable. There is referral to appropriate agencies if necessary. Sufficient space is provided for private meetings and discussions. While it is not a program requirement a social worker or other staff may contribute to the resident's care plans by indicating personal strengths that can be used to build upon.	Nursing Services SNF 405.1124 ICF 442.338 Activities SNF 405.1131 ICF 442.345(a)(c) (d) Physicians Services SNF 405.1123(b) ICF 442.346 Patient Care Management SNF 1124(d) ICF 442.346 Physical Environment SNF 405.1130(b) ICF 442.344(c)

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F233-238 (cont'd) F238 2. If financial assistance is indicated, arrangements are made promptly for referral to an appropriate agency.		- Can you tell me about your life here? What do you do in a usual day? - Are things like getting up, bathing, dressing, eating, done at the same time for everyone? - If you could change some things about living here, what would you change? Ask Social Worker/Nurse -When the social worker is readily available, delete "ask the nurse". -How often is the resident seen by a social worker?" - Who is responsible for identifying the resident's: + social and emotional needs + family and home situation + problems and needs + financial needs - How are needs identified and reported? - Does resident participate in the development of his/her care plan? - Ask nursing how often the social worker sees resident. - Does the social worker discuss residents needs/problems with nursing staff if there is a need for nursing to be involved?	- Plan of care, social service notes, reflect the current status of the resident. - There is evidence that the residents mental status has been considered when plan of care was developed. - Vision and hearing problems have been addressed. - Plan of care addresses residents needs as observed by the surveyor and stated by the resident. - Notes and plan indicate that needs have been re-evaluated and care plan changed as necessary. - There is evidence that the problems and needs of the family have been addressed. - There are indications that a referral has been made to the appropriate agency and a statement describing why. - There is documentation from the outside agency indicating what actions were taken and any plan for follow-up.		

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F233-238 (cont'd)		- How is physician notified and involved in plan of care? - Ask social service staff their role, function, and what services they provide. - Ask staff what referral services are available. - If services are being provided by outside resource, are resources documented work service? - Ask social service staff about their background and education. - If there is a consultant ask staff: + How often does the person come? + How long do they stay? + What does the person do while in the facility? + What assistance, consultation is being provided? + Ask social service staff if adequate space is provided for them by the facility to conduct private interviews and meetings.	- The time period between date of referral and date of services is reasonable and if not, there is evidence of follow-thru by staff. - The outside agency has documented their involvement and activities. - Plan of care demonstrates awareness of behavior, articulates the reasons for it, and indicates in the plan of care an approach to the behavior. - Assessment should contain: + a flexible approach to each resident (should be individualized). + awareness of a mental status evaluation. + resident history. + family availability for planning, resident support, etc. + identification of problems resulting from placement. + recent social adjustment. + discharge planning. - The record reflects	- There is documentation of collaboration between nursing and social work for meeting emotional needs.	Patient Care Management 405.1124(d)

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F233-238 (cont'd)			Social Service intervention with family and resident, i.e., grief and bereavement counseling. - Review integrated plan of care for: + Plan for concerted social services. + Plan for supportive services for adjustment. - Adjustment goals. - Interventions for specific conditions.		
Activities F239 SNF 405.1131 F240 SNF 405.1131(b) F241 ICF 442.345 F242 1. An ongoing program of meaningful activities is provided based on identified needs and	General level of activities throughout the facility, as well as in specifically designated areas. How many residents are lying on their beds or sitting in chairs staring at the walls during waking hours? What is the level of residents interest in activities they are doing? Are residents positioned correctly for activity?	- How does he/she spend the day? - Of the activities resident has during the week, what does he/she enjoy most/least? - If has none, why? - Has staff asked about his/her interests? Suggested specific activities or people to get acquainted with in response to interests? - What organized activities has he/she participated in this past week? - How does resident find out about upcoming programs or happenings?	Activities Assessment Interests of the resident (past and present) are identified as to resident's current capabilities and necessary adaptations to pursue their interests. Documentation that information about social history, medical problems and limitations impacting residents' activities have been communicated to activities personnel and used in assessment and development of activities portion of care plan.	Are each resident's personal interests known? If not, what actions are being taken to identify them? Residents in facility 60 days should not be without some identified interests. Are each resident's needs identified? If not, what actions are being taken to identify them? Have medical contraindications been identified in the care plans? Needs and contraindications of residents in the facility more than 30 days should be known and/or have a plan of action.	Nursing Services 405.1124 442.319 Social Services 405.1130 442.344 Special Rehabilitative Services 405.1126 442.363 Physician Services 405.1123 442.329

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F242-(cont'd) interests of each resident. It is designed to promote opportunities for engaging in normal pursuits, including religious activities of their choice, if any.	Are needed personal equipment (e.g., splints, glasses) and adaptations for limitations and safety (e.g., cardholder, goggles, footrests) used in activities?	- Does resident get out of facility to activities? - Does resident have problems getting to activities? If so, does the staff assist? - Does the staff encourage residents to go to activities? - Does resident participate in Resident Council? - Does resident have free choice of activities? - What kind of activities do bedfast residents engage in? Ask Resident: - Have you ever had difficulty in having private visits? Give examples.	- Needs of the resident in the following areas are identified: + social interaction + creative expression + work and service opportunities + intellectual stimulation or activities adaptation + physical exercise + spiritual or religious expression - Plan of care Used all available information about: + interests + needs + indications and contraindications for activities from other assessments + physician orders and progress notes	Does each resident's activities promote his physical, social and mental well-being?	Physical Environment 405.1134 442.329 Infection Control 405.1135 442.328 Resident Rights 405.1121(k) 405.311 Medical Records 405.1132 405.318 Patient Care Management 405.1124(d) 442.341
F243 2. Unless contraindicated by the attending physician, all residents are encouraged to participate in activities.					
F244 3. The activities promote the physical, social and mental well being of the residents.					

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LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F245 4. Equipment is maintained in good working order. F246 5. Supplies and equipment for activities of interest are available. INTENT Each resident has individual and/or group activities to meet activities needs through his interests daily.	Is lighting adequate throughout the facility for activities in which residents are engaged? Do men and women have activities of interest to them? Do residents communicate with each other in activities? Are methods of communicating upcoming activities appropriate to the resident populations? Specific observation for physically impaired/alert residents: Activities adapted to meet specific needs of the resident. Alert residents have activities of interest and at their cognitive functional level. Specific observations for confused/disoriented, emotionally disturbed and mentally retarded residents: There are current calendars, clocks and patients	Ask Nursing/Activity Staff - Do they know the interests of residents under their care? TV programs they like? Activities they want to participate in today/this week? - Do they know the personal equipment needed (e.g., glasses, hearing aids, reacher)? - Do they know the adaptive equipment used by residents for specific activities (e.g., talking books, built up tools)? - Do they talk to residents to identify new interests and report these and "dislikes" to activities personnel? How? - What is staff's involvement with individual and group activities of residents in their care? - How do they determine interests of residents who have difficulty communicating? - What activities does resident participate in regularly? Which activities does he/she enjoy most/least?	Activities notes spell out implementation of plan, resident's reactions to specific activities, approaches, and people. Residents' participation in individual and group self-started and organized structured and unstructured activities timespent. Evaluation of plan of care for: changes in interests; changes in precautions, changes in needs, new problems, approaches, etc. Plans are revised as needed.	Are equipment and supplies to meet residents interests available and maintained in good working order? Are residents evaluated periodically with emphasis on participation levels and desire for new activities? Are plans readjusted if they do not reach desired outcomes? Residents in the facility more than 60 days should have at least two activities per week of interest to them personally.	

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F246 (cont'd)	and patients names or symbols visible to all the residents. Staff consistently use techniques such as reality orientation, empathy, and/or validation therapy as per each individual's needs. Resident has familiar items if available in room (e.g., family pictures, artwork, afghan, chair from home). Residents in restraints have activities of interest geared to their abilities when restrained (e.g., table-top activity, music, radio, reading and writing material; when out of restraints (e.g., walks, exercise, group, toileting). Small group and one-on-one involvement with staff reinforcing appropriate responses. Staff reaction to resident behavior during activities (e.g., crying, whining, demanding, nonverbal, agression,	- If he/she does not participate, why? - Which activities appear to relax/calm the resident? Excite him/her? - How does staff manage maladaptive behavior (e.g., abusive, disruptive, combative)? - Is direct care staff involved in resident activities? How? When (weekends, evenings)? - Does resident have one-to-one assistance in activities? - How many residents have few activities a day of interest to them as individuals? - Why do these residents have so little interest? - What is your plan to find more activities of interest to them that will meet their needs? - What types of residents seem not to be interested in activities? - How many (who) residents have only passive activities?			

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F 246 (cont'd.)	loudness). __Specific observation for comatose or teminally ill resident__: - Appropriate items for sensory enrichment in room (e.g., TV, radio, adequate lighting) - Resident placed in supportive living environment (e.g., around people, in hall, activities room, sunshine, fresh air), when appropriate to the resident needs and consistent with the resident's choice.	- How do you adapt activities for needs of residents who are: - confused/disoriented - emotionally disturbed - mentally retarded - physically impaired but alert - terminally ill? - Are community volunteers utilized in the activities program? In what way? - Are the residents encouraged to offer suggestions for new activities? If so, what activities have been instituted as a result?		Resident may refuse to participate in activity. However if the activities are part of a diagnostic or therapeutic program, the resident is responsible for assisting in the selection of mutually acceptable alternative activities.	
	__Specific observation of environment for conducting activity program__: - Adequate lighting. - Functional area is appropriate for activities of interest (e.g., religious services, arts and crafts, cooking, reading, TV watching, card playing, parties, discussion groups, gardening).	- How they manage maladaptive behavior (e.g., abusive, disruptive, combative)? - How do they help depressed residents (e.g., tearful, emotionally labile)?			

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F246 (cont'd)	- Multi-purpose room use and timing of activities does not conflict. - Outdoor activity area. - Functional furniture, indoors and outdoors. - Evidence of free choice activities: - newspapers - magazines - record player - radios - games - TV's - reading - sewing - personal visits - church services - Activities, equipment and supplies are appropriate and sufficient to meet interest of residents. - Activities equipment and supplies sufficient for conducting activities. - Activities equipment clean, safe, and in working order. - Residents rooms contain independent project materials, as appropriate. - Residents have access to the total activity environment (e.g., lobby, sunroom, dayroom, porch, dining room).				

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
MEDICAL RECORDS F247 SNF 405.1132				All information required is present in the record. Does the record document all observable resident needs/problems?	
Content F248 SNF 405.1132(c)					
F249 ICF 442.318(a)(c)					
F250 1. The medical record contains sufficient information to identify the resident clearly to justify diagnoses and treatment and to document results accurately.					
F251 2. The medical record contains the following information.					

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F251 (cont'd) a. Identification information.					
F252 b. Admission data including past medical social history.					
F253 c. Transfer form, discharge summary from any transferring facility.					
F254 d. Report of resident's attending physician.					
F255 e. Report of physical examinations.					

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F256 f. Reports of physicians' periodic evaluations and progress notes.					
F257 g. Diagnostic reports and therapeutic orders.					
F258 h. Reports of treatments.					
F259 i. Medications administered.					
F260 j. An overall plan of care setting forth goals to be accomplished through each service's designed activities, therapies and treatments.					

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F261 k. Assessments and goals of each service's plan of care.					
F262 l. Treatments and services rendered.					
F263 m. Progress notes.					
F264 n. All symptoms and other indications of illness or injury including date, time and action taken regarding each problem.					

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F264 (cont'd) INTENT Brings together all resident information. Reflects the care being given to the residents and helps all care givers to make decisions on care needed.					
TRANSFER AGREEMENT F265 SNF 405.1133		Ask Staff: - What is the routine information you provide to a new facility when you transfer a resident? - Who provides this?	Review information on medical record of resident who was temporarily transferred and is again back in the facility.	All pertinent resident information must be documented on the medical record at the time of transfer.	Patient Rights 404.1121(k) 442.311
F266 SNF 405.1133(a)			Look at physician and nursing progress notes of above residents to determine if the timeliness of transfer was consistent with accepted standards of care.	The resident was not injured in any way by a delay in the transfer process.	
F267 ICF 442.316					
F268 A. Whenever the physician determines that a transfer is medically appropriate between a			Does facility have an agreement with a hospital? Not required if hospital under same ownership, direction and in same campus.		

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F 268 (cont'd) hospital or a facility providing more specialized care and the nursing facility, admission to the new facility shall be effected in a timely manner.			Is transfer form complete with all data, with appropriate signatures? Does the medical record indicate that adequate and pertinent aspects of the discharge planning portion of the patient care plan accompany the patient on transfer?		
F269 B. Information necessary for providing care and treatment to transferred individuals is provided.					
PHYSICAL ENVIRONMENT F270 SNF 405.1134					

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F271 A. Nursing Unit SNF 405.1134(d)				Medication preparation and storage areas provide adequate space and light to prepare medication and to store medication and needed supplies.	Nursing Service 405.1124(g) 442.337 Infection Control 405.1135 Governing Body 442.325 Resident Rooms 405.1134(e) 442.325
F272 1. Unit properly equipped for preparation and storage of drugs and biologicals.	There is adequate light to prepare medications. There is sufficient space to prepare medications for administration in a safe and effective manner.	Ask Nursing Staff: - What do you use the medication room (area) for? - Where is the handwashing sink? - Do you have enough, convenient storage area for I.V. fluids and medications needing refrigeration.		Light is available when and where the medication cart is in use. A medication refrigerator is available and does not contain patient or employee snacks. Juice, etc., used in administering medication is allowed.	
F273 2. Utility and storage rooms are adequate size.	There is sufficient space for storage of medications. Unit dose carts are protected from tampering and theft.	- Where are the keys for the medication room and unit dose carts? - Do you feel you have adequate storage space for supplies and equipment? - If no, what problems does that cause?		Clean and dirty areas must be separated, preferably in separate rooms. Storage space must be available for bulky items and supplies so that they can be stored without blocking corridors and exits.	
F274 3. The unit is equipped to register resident calls with a functioning communications system from resident areas including rooms and toilets and bathing facility.	Medications are stored in a locked area. Refrigeration facilities are available for medications. There is sufficient storage space for I.V. fluids. Handwashing facilities are readily accessible either in the medication preparation area or adjacent to it.	- Does the resident call system function properly? Ask Residents: - Do the call bells in your room and in the toilets and bathing areas always work?		Medications are protected from unauthorized use. Call bells must be in working order and must be present in all resident bedrooms, toilets and	

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F274 (cont'd)	Audible call system is on and working. Long cords are available for chair bound patients.	- If no: - How often is it that they do not work? - How long does it take to get them fixed?		bathing areas. Audible signals, if in the system, must be in working order and turned on.	
B. Dining and activities area F275 SNF 405.1134(g) F276 ICF 442.329	Area is clean and well maintained. There is sufficient space between tables to allow for safe passage of wheelchairs and residents with walkers, canes and other assistive devices.	Ask Residents: - Is there enough room between tables to allow you to feel safe in getting to your table? - Can you sit comfortably in your wheelchair at the table? - How is the lighting and ventilation level for you? - Are sitting preferences permitted? - Do you go to the dining room for meals?		Regulations clearly set out conditions for compliance. Refer to the regulations.	Dietetic Services 405.1125 442.331 Patient Activities 405.1131 442.345
F277 1. The facility provides one or more clean, orderly, and appropriately furnished rooms of adequate size, designed for resident dining and resident activities.	Table height or design allows residents in wheelchairs to sit a normal distance from the table. Lighting and ventilation in the dining/activity areas is provided according to recommended standards. A multi-purpose room should not be used for storage of items such as beds, mattresses, boxes, etc.				

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F278 2. Dining and activity rooms are well lighted and ventilated.	Are dining areas utilized at meal service?				
F279 3. Any multi-purpose room used for dining and resident activities has sufficient space to accommodate all activities and prevent their interference with each other.					
F280 SNF 405.1134(e) Indicators C&D apply to SNFs					

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
C. Resident Rooms F281 ICF 442.325	Observe rooms and furnishings for maintenance, cleanliness and safety. Look for dust/dirt on lights, high surfaces, under heating units, and in corners. Use a flashlight.	Ask Residents: - Is your room kept clean? Who cleans it? When, and how often? - Is your bed, chair, and other furniture and fixtures kept in good repair? - Do you feel you have enough privacy? - What personal belongings are you allowed to have? - Is the lighting in your room sufficient for you? - Is your chair comfortable? - When do you permit staff to clean you room? - When do you ask staff not to clean you room?		Refer to the regulations.	Resident Rights 405.1121(k)(1)(5) (9)(13) 442.311(a)(d)(2) (g)(1)(2) (6)(k) Physical Environment 405.1134(d)(e) 442.326
F282 1. Single rooms have at least 100 sq. ft.	Are beds, lights, plumbing all in working order?				
F283 2. Multiple resident rooms have no more that 4 residents and at least 80 sq. feet per resident.	Observe for all regulatory requirements as noted to the left. Are privacy curtains present, and appropriate to maintain resident privacy?				
F284 3. Each room is equipped with or conveniently located near toilet and bathing facilities.	Test several call lights. Are call lights within reach, including emergency lights in toilets and bathing areas? Are toilet and bathing facilities appropriate in number, size, and design to meet resident needs?				
	What personal belongings do residents have in their rooms? Is there				

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F285 4. There is a capability of maintaining privacy in each.	sufficient storage and security for their belongings?				
F286 5. There is adequate storage space for each resident.					
F287 6. There is a comfortable and functioning bed and chair, plus a functional cabinet and light.					

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F288 7. The resident call system functions in resident rooms.					
F289 8. Each room is designed and equipped for adequate nursing care and the comfort and privacy of residents.					
F290 9. Each room is at or above grade level.					
F291 10. Each room has direct access to a corridor and outside exposure.					
Exception: Not required for ICF residents.					

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
D. Toilet and bath facilities F292 ICF 442.326 F293 1. Facilities are clean, sanitary and free of odors.	Are there adequate numbers of toilets, baths, and showers for the residents that are accessible to, and functional for all residents? Are these conveniently located in or near resident rooms? Check for water on floors of bath and shower rooms.	Ask Residents: - When was your last bath? The one before? - What safety precautions are used for getting in and out of the bathtub? - What equipment is needed to get in and out of the tub, and how do you feel about it? - How do you get your wheelchair into the toilet or bathroom?	Bathing schedule for patients in your indepth review.	Privacy is maintained for residents in toilet and bathing areas. Toilet and bathing areas are clean. Water is removed from floors immediately upon completion of bathing. Hot water is within the acceptable temperature range.	
F294 2. Facilities have safe and comfortable hot water temperatures.	Is privacy provided? Are facilities clean, sanitary and free of unpleasant odors?	- When, if ever, do you refuse to be bathed?		Soap, toilet paper and towels are available in the bathrooms.	
F295 3. Facilities maintain privacy.	Are bathrooms equipped with soap, toilet tissue, towels, etc.? Hot water is between 110-120 degrees or the acceptable State level. Hot water temperature control must be maintained. Single use, disposable towels should be available for handwashing purposes.			Grab bars are present and securely fastened to the wall. Ventilation and lighting systems are correctly functioning. Plumbing and other fixtures are in good condition.	
F296 4. Facilities have grab bars and other safe guards against slipping.	Note also condition of grab bars, plumbing and fixtures. Bath areas are not used for storage.				

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F297 5. Facilities have fixtures in good condition.					
F298 6. The resident call system functions in toilet and bath facilities.			Facility has appropriate arrangements for providing social services, either using: - outside resources (contract or consultant services) - qualified facility personnel under a clearly defined plan.		
E. Social Service Area	Does the social worker have a locked file available?	Ask Resident: - Does the social worker see you in a private room or in your own room? - If in your own room, do you feel that you have enough privacy?		Refer to regulations.	
F299 SNF 405.1130(b) ICF 442.344	Where are social service interviews and clerical functions performed?				
F300 1. Ensures privacy for social service interviewing.	Are rooms in areas easily accessible to residents?				
F301 2. Adequate space for clerical and interviewing functions is provided.					
F302 3. Facilities are easily accessible to residents and staff.					

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F. Therapy areas F303 SNF 405.1126(a)	Therapy areas are accessible to all residents needing the facilities. Space allows for safe maneuvering of residents and equipment and staff.	Ask Resident: - Do you feel that the equipment you use is safe? - Do you have enough room for your treatment?	Refer to regulations.		
F304 ICF 442.328(a)	All residents are able to be observed and supervised during therapy.	Ask Therapy Staff: - Is your equipment adequately maintained? - Do you have enough room to safely and adequately provide treatment?			
F305 1. Space is adequate for proper use of equipment by all residents receiving treatment	Equipment has labels (stickers, etc.) to indicate proper maintenance. All equipment fastened to floor and walls is secure.				
G. Facilities for Special care F307 SNF 405.1134(f)	Are therapy areas properly ventilated to effectively reduce heat, moisture and odors?	Ask Supervisory personnel: - What room(s) do you use for isolation? - What is your procedure if the room is already occupied when you need it for isolation? - Will you show me the signs you use to identify the isolation room?		Rooms meeting the regulatory requirements are available in the facility. There is a procedure that is implemented when an isolation is needed, but it is already occupied. Isolation signs are visable and clearly convey their intended message.	Resident Rights 405.1121(k)(4) 442.311(c)(2) Infection Control 405.1135(b)
F308 ICF 442.328(b)	Are private rooms available that meet regulatory criteria. If a resident is infected and in isolation, are precautionary signs posted, and are they legible and understandable?				

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F309 1. Single rooms with private toilet and handwashing facilities are available for isolating residents.					
F310 2. Precautionary signs are used to identify these rooms when in use.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
H. Common Resident Areas F311 SNF 405.1134(j) F312 ICF 442.324 F313 1. All common resident areas are clean, sanitary and free of odors. F314 2. Provision is made for adequate and comfortable lighting levels in all areas. F315 3. There is limitation of sounds at comfort levels.	Use senses - sight, hearing, olfactory when surveying common areas as lounges, lobby, corridors. Note levels of lighting for both reading and non-reading areas. Is it bright enough but without glare? Are areas clean and without offensive odors? Do background sound levels allow for ease of communication and comfort for residents/visitors? Do residents seem comfortable with the room temperature - note the use of several layers of clothing, many residents fanning themselves, etc. Are handrails on each side of the corridor and are they secure? Are smoking/no smoking areas designated?	Ask Residents: - Do you think that the lounges and corridors are usually clean? - Do they have any unpleasant odors? - Is the lighting level comfortable for you to read? Is it adequate for you to feel safe walking? - Do you have any difficulty with the noise level? - Is the temperature usually comfortable for you? - Do you feel there is adequate ventilation? - Are there handrails in all of the corridors? - Are they securely fastened to the wall? Ask Supervisory Staff: - If there is a water main break or other interruption in the water supply, how do you obtain water for essential areas and duties?		- Floors and furniture should appear clean - free of gross contamination. - Residents should have lighting bright enough to safely negotiate corridors, lounges, etc., and in reading area, be bright enough to read. But the brightness should be free of glare. Remember, the elderly need a higher level of lighting as their sight diminishes. - Except for times when a louder level of sound is necessary for communication, sounds should be unobtrusive and "comfortable". - Room temperature comfort levels vary widely, and in general the elderly will require a higher temperature for comfort than younger people. Use information from resident interviews and your observations to determine if the temperature is "comfortable" for most residents. - All corridors in	Infection Control 405.1135(c)

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F316 4. A comfortable room temperature is maintained.				resident-used areas are equipped with handrails on each side. These rails securely fastened provide the residents with a firm support. - Supervisory staff are able to tell you how they will obtain water for drinking, cleaning/bathing of residents, and other essential functions if their normal water supply is interrupted.	
F317 5. There is adequate ventilation thru windows or mechanical measures or a combination of both.					
F318 6. Corridors are equipped with firmly secured handrails on each side.					
F319 7. Staff are aware of procedures to ensure water to all essential areas in the event of loss of normal supply.					Disaster Preparedness 405.1136 442.313

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
I. Maintenance of Building and Equipment F320 SNF 405.1134(i)	- Ceiling and floor tile in good condition - Paint in good repair - No holes in walls - Look for rat and other rodent trails outside and inside - Preventive maintenance program for all equipment is followed - Wheelchairs not stored in hallways, bathrooms, etc. - Window screens are in good repair - Check overbed tables, wheelchairs, etc., for cleanliness and operation	Ask Staff: - How many housekeeping staff are available? - How late are housekeepers on duty during the week? - How is weekend coverage different? Ask Resident: - What if any problems have you had with special equipment you need to use?			Physical Environment 405.1134(d)
F321 1. The interior and exterior of the building are clean and orderly.					
F322 2. All essential mechanical and electrical equipment is maintained in safe operating condition.					
F323 3. Sufficient storage space is available and used for equipment to ensure that the facility is orderly and safe.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F324 4. Resident care equipment is clean and maintained in safe operating condition.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Indicator J applies to ICFs. J. Dietetic Service Area F326 SNF 405.1134(h)	Observe for - needed space to carry out routine operations - maintenance of working surfaces equipment, utensils, and serving dishes - operable dish washer machine. - 3-sink method of pot/dish washing properly carried out/or written procedure posted - operable and clean exhaust fan - stored dishes and pots are free of baked-on food particles and chipped/cracked surfaces - food stored off floor - protective covers for fluorescent lights - handwashing sink readily accessible	Ask Staff: - What have you been trained to do? - What type of dishwasher machine do you have? How does it operate?	The proper temperature for the Dishwasher wash cycle is 150-160 degrees Fahrenheit. The dishwasher rinse cycle is acceptable at temperature of 180 degrees Fahrenheit or when there is a change in the temperature-sensitive tape (thermolabel). The individual manufacturers' specifications may countermand these instructions, particulary in the case of chemical sanitization.		Dietetic Services 405.1125(g) 442.331(b)
F327 1. Kitchen and dietetic service areas are adequate to insure proper, timely service for all patients.					
F328 2. Kitchen areas are properly ventilated, arranged, and equipped for storage and preparation of food as well as for dish and utensil cleaning, and refuse storage and removal.					

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Indicator K applies to ICF K. Dieteary Staff Hygiene F329 SNF 405.1125(f)	Observe the following: - cleanliness of hands, fingernails, hair, clothing - use of hair restraint - whether employees wash hands with soap and water after using the toilet, smoking, blowing their nose, touching raw meat, poultry or eggs - employees using hands to mix food when utensils could be used - employees using the same spoon more than once for tasting food while preparing, cooking, or serving.	Ask Staff: - What happens when you report to work with a cold, a cut or sore on your hand? - Where is handwashing sink for dietary staff? - Do you use disposable plastic hand covers? If so, when? - Where are your serving utensils located? - What are temperatures for the refrigerators and freezers? Who is responsible for checking temperatures? - Do you have thermometers to check water and food temperatures? (ask them to demonstrate how they take temperatures)			Dietetic Services 405.1125(e)(f)(g)
F330 1. Dietetic service personnel practice hygenic food handling techniques.					
Indicator L applies to ICF L. Dietary Sanitary Conditions F331 SNF 405.1125(g)	Verify that: - hot foods are 140 degrees or above - cold foods are 45 degrees or lower (*note: food held for more than 2-3 hours between 60 and 125 degrees may not be safe to eat) - cooked meats held longer than 72 hours are used, discarded or put in the freezer				
F332 1. Food is stored, refrigerated, prepared, distributed, and served under sanitary conditions.					
F333 2. Waste is disposed of properly.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F333 (cont'd)	- check that the refrigerators are equipped with an accurate thermometer - food does not have an "off" or bad odor - cracked eggs are discarded - foods are dated and then stored as to their preparation date. Observe that waste is in covered containers, bagged and tied for disposal, and that dumpsters are covered.				

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
L. Emergency Power F334 SNF 405.1134(b)	Is an emergency generator available?			As per regulations and covered by the Life Safety Code surveyor	
F335 1. An emergency source of electrical power necessary to protect the health and safety of residents is available.	Test generator under full load conditions. Check items of emergency power: - lighting - fire detection - alarms - extinguishing systems - life support systems Transfer time from normal power to emergency power to occur within 10 seconds.				
F336 2. Emergency power is adequate at least for lighting in all means of egress; equipment to maintain fire detection, alarm, and extinguishing systems; and life support systems.	Check for gounded extension cords at nurses stations. Where are emergency outlets?				

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F337 3. Emergency power is provided by an emergency generator located on the premises where life support systems are used.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Infection Control F338 SNF 405.1135	- Observation of dressing technique to identify if infection control principles are being adhered to: - sterile technique - sterile/clean field - disposal of dressing - handwashing - use of gloves	Ask Staff: - What type of dressing changes are you performing? - How often are dressings changed? - Why is resident on isolation/precautions? - Do laundry/housekeeping personnel/aides know procedures? Ask Resident: - Do you know why you have dressings? - Do you know why you are on isolation/precautions? - Do you have clean linen when you need it?	Review records of residents selected for indepth review for infection.	Compliance will be based mainly on your observations. Deficiencies will be cited if you see: - breaks in aseptic or isolation technique - clutter or unclean conditions that would cause unsafe conditions - inadequate supplies of linen to provide proper care and comfort for residents - inadequate techniques for handling clean and dirty linen - evidence of insect or rodent infestation - use flash light to check for roaches in closets, cabinets.	Nursing Services 405.1124 442.338
A. Infection Control F339 SNF 405.1135(b)					
F340 Aseptic and isolation techniques are followed by all personnel.	- Observation of isolation precautions: - signs - linen, double bagged - soiled linen, double bagged - gowns/masks - gloves - handwashing - disposable dishes - information for visitors				
B. Sanitation F341 SNF 405.1135(c)					
F342 The facility maintains a safe, clean, and orderly interior.	- Procedures followed by: - Laundry - Housekeeping How is dirty linen transported to laundry or holding area?				
C. Linen F343 SNF 405.1135(d)	Do aides wash hands after cleaning dirty linen? How do aides handle clean/dirty linen while changing beds?				

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F344 ICF 442.327					
F345 1. The facility has available at all times a quantity of linen essential for proper care and comfort of residents.					
F346 2. Linens are handled: stored, processed, and transported in such a manner as to prevent the spread of infection.					
D. Pest Control F347 SNF 405.1135(e)	Look for evidence of insect or rodent presence (mouse or rat droppings, roaches, ants, flies around trash) - Screen doors closed - Windows that can be opened have screens that are in good repair	Ask Staff: - Have you seen insects (roaches, ants, flies, etc.)? - Have you seen rodents and/or droppings? - What foods are residents permitted to keep in their rooms?			
F348 ICF 442.315(c)					
F349 The facility is maintained free from insects and rodents.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
DISASTER PREPAREDNESS F350 SNF 405.1136 F351 SNF 405.1136(a) F352 ICF 442.313	- Disaster plan is located at each nursing station. - Evacuation plans posted in each smoke compartment.	Ask Residents: - Do you know what to do in case of fire? - How often do you rehearse it? Ask Staff: - What are your responsibilities at a fire drill? - What is the facilities disaster plan? (Specify types, [(e.g., fire, flood, etc.)] - How you undergone disaster training? - Have you participated in a fire disaster drill? When? - How frequently are drills held? - Have you been trained/instructed in the use of fire equipment, fire containment methods? - Have you been trained in transfer or casualties and routes? - How would staff meet emotional needs of residents during/following a "disaster", e.g., fire		A disaster plan is available and facility staff know their roles.	Physical Environment 405.1134(a)(b) 442.321
Indicators A and B apply to ICFs.					
A. Disaster Plan F353 1. Facility staff are aware of plans, procedures to be followed for fire, explosion or other disaster.					
F354 2. Facility staff are knowledgeable about evacuation routes.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F355 3. Facility staff are aware of their specific responsibilities in regard to evaluation and protection of residents.					
F356 4. Facility staff are aware of methods of containing fire.					
B. Drills F357 SNF 405.1136(b)					
F358 1. All employees are trained as part of their employment orientation in all aspects of preparedness for any disaster.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F359 2. Facility staff participate in ongoing training and drills in all procedures so that each employee promtly and correctly carries out a specific role in case of a disaster. INTENT To ensure a clean, safe environment for residents.					

PART 489—PROVIDER AGREEMENTS UNDER MEDICARE

Subpart A—General Provisions

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Subpart F—Denial of Payments to SNF's for New Admissions; Withholding of Payment

489.60 Denial of payments for new admissions.
489.62 Procedures for denial of payments.
489.64 Duration of denial of payments and subsequent termination.
489.66 Withholding of payment for failure to make timely utilization review.

AUTHORITY: Secs. 1102, 1861, 1864(m), 1866, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395x, 1395aa(m), 1395cc, and 1395hh).

SOURCE: 45 FR 22937, Apr. 4, 1980, unless otherwise noted.

Subpart A—General Provisions

§ 489.1 Statutory basis.

This part implements section 1866 of the Social Security Act. Section 1866 specifies the terms of provider agreements, the grounds for terminating a provider agreement, the circumstances under which payment for new admissions may be denied, and the circumstances under which payment may be withheld for failure to make timely utilization review. The following other sections of that Act are also pertinent.

(a) Section 1861 defines the services covered under Medicare and the providers that may be reimbursed for furnishing those services.

(b) Section 1864 provides for the use of State survey agencies to ascertain whether certain entities meet the conditions of participation.

(c) Section 1871 authorizes the Secretary to prescribe regulations for the administration of the Medicare program.

[45 FR 22937, Apr. 4, 1980, as amended at 51 FR 24492, July 3, 1986]

§ 489.2 Scope of part.

(a) Subpart A of this part sets forth the basic requirements for submittal and acceptance of a provider agreement under Medicare. Subpart B of this part specifies the basic commitments and limitations that the provider must agree to as part of an agreement to provide services. Subpart C specifies the limitations on allowable charges to beneficiaries for deductibles, coinsurance, copayments, blood, and services that must be part of the provider agreement. Subpart D of this part specifies how incorrect collections are to be handled. Subpart F sets forth the circumstances and procedures for denial of payments for new admissions and for withholding of payment as an alternative to termination of a provider agreement.

(b) The following providers are subject to the provisions of this part:

(1) Hospitals.

(2) Skilled nursing facilities (SNFs).

(3) Home health agencies (HHAs).

(4) Clinics, rehabilitation agencies, and public health agencies.

(5) Comprehensive outpatient rehabilitation facilities (CORFs).

(6) Hospices.

(c) Those listed in paragraph (b)(4) of this section may enter into provider agreements only for furnishing outpatient physical therapy and speech pathology services.

[45 FR 22937, Apr. 4, 1980, as amended at 47 FR 56297, Dec. 15, 1982; 48 FR 56036, Dec. 15, 1983; 51 FR 24492, July 3, 1986]

§ 489.3 Definitions.

For purposes of this part—

Immediate jeopardy for Medicare SNFs means a situation in which a facility's noncompliance with one or more conditions of participation poses a serious threat to patents' health and safety such that immediate corrective action is necessary.

Provider agreement means an agreement between HCFA and one of the providers specified in § 489.2(b) to provide services to Medicare beneficiaries and to comply with the requirements of section 1866 of the Act.

[48 FR 39837, Sept. 1, 1983, as amended at 51 FR 24492, July 3, 1986]

§ 489.10 Basic requirements.

(a) Any of the providers specified in § 489.2 may request participation in Medicare. In order to be accepted, it must meet—

(1) The conditions of participation set forth elsewhere in this chapter; and

(2) The civil rights requirements specified in 45 CFR Parts 80, 84, and 90.

(b) The State survey agency will ascertain whether the provider meets the conditions of participation and make its recommendation to HCFA.

§ 489.11 Acceptance of a provider as a participant.

(a) *Action by HCFA.* If HCFA determines that the provider meets the requirements, it will send the provider—

(1) Written notice of that determination; and

(2) Two copies of the provider agreement.

(b) *Action by provider.* If the provider wishes to participate, it must return both copies of the agreement, duly signed by an authorized official, to HCFA, together with a written statement indicating whether it has been adjudged insolvent or bankrupt in any State or Federal court, or whether any insolvency or bankruptcy actions are pending.

(c) *Notice of acceptance.* If HCFA accepts the agreement, it will return one copy to the provider with a written notice that—

(1) Indicates the dates on which it was signed by the provider's representative and accepted by HCFA;

(2) Specifies the effective date of the agreement; and

(3) If the agreement is with a SNF, specifies the term of the agreement.

§ 489.12 Decision to deny an agreement.

(a) *Bases for denial.* HCFA may refuse to enter into or renew an agreement for any of the following reasons:

(1) Principals of the provider have been convicted of fraud (see § 420.204 of this chapter);

(2) The provider has failed to disclose ownership and control interests in accordance with § 420.206 of this chapter; or

(3) The provider has been adjudged bankrupt or insolvent.

(b) *Effect of bankruptcy or insolvency.* (1) HCFA will not enter into an agreement with a provider that has been adjudged insolvent or bankrupt under appropriate State or Federal law, or against which there is pending a court proceeding to make a judgment concerning this matter. The reason for denial is that the provider is unable to give satisfactory assurances of compliance with the requirements of title XVIII of the Act.

(2) If a provider who is participating and receiving payments under Medicare is subsequently adjudged insolvent or bankrupt by a court of competent jurisdiction, HCFA will not terminate its participation in the program because of that financial condition.

However, the intermediary will adjust payments to the provider (as specified in § 413.64(i) of this chapter) to preclude overpayments.

(c) *Compliance with civil rights requirements.* HCFA will not enter into a provider agreement if the provider fails to comply with civil rights requirements set forth in 45 CFR Parts 80, 84, and 90.

[45 FR 22937, Apr. 4, 1980, as amended at 51 FR 34833, Sept. 30, 1986]

§ 489.13 Effective date of agreement.

(a) *All Federal requirements are met on the date of the survey.* The agreement will be effective on the date the onsite survey is completed (or on the day following the expiration date of a current agreement) if, on the date of the survey, the provider meets all Federal health and safety standards, and any other requirements imposed by HCFA.

(b) *All Federal requirements are not met on the date of the survey.* If the provider fails to meet any of the requirements specified in paragraph (a) of this section, the agreement will be effective on the earlier of the following dates:

(1) The date on which the provider meets all requirements.

(2) The date on which the provider submits a correction plan acceptable to HCFA or an approvable waiver request, or both.

§ 489.15 Time limits on agreements with skilled nursing facilities (SNFs).

(a) *Basic limitation.* An agreement with a SNF must be for a specified term, determined by HCFA in accordance with paragraphs (b) and (c) of this section.

(b) *SNF in full compliance.* If the SNF is in full compliance with the conditions of participation specified elsewhere in this chapter, the term must be 12 calendar months.

(c) *SNF not in full compliance*—(1) *Alternatives.* A SNF that is not in full compliance may be issued a restricted agreement or a conditional agreement.

(2) *Restricted agreement.* This agreement must:

(i) Specify a date by which corrections must be made;

(ii) End no later than the 60th day following the date specified for correction of deficiencies; and

(iii) Be for a term that, including the 60-day period, is 12 months or less.

(3) *Conditional agreement.* This agreement must:

(i) Be for 12 months;

(ii) Specify a date for correction of deficiences that is no later than the end of the 10th month; and

(iii) Provide for automatic cancellation on the 60th day following the date specified for correction, unless HCFA determines that all deficiencies have been corrected or the SNF has made substantial effort and progress and has submitted an acceptable revised correction plan.

(d) *Extention of the agreement.* An agreement may be extended for 60 days if—

(1) HCFA determines the extension will not jeopardize the health and safety of beneficiaries; and

(2) The extension is needed—

(i) To prevent irreparable harm to the SNF or hardship to the beneficiaries receiving services from the SNF; or

(ii) To enable HCFA to determine whether the SNF is in compliance with the conditions of participation.

§ 489.16 Nonrenewal of agreements with SNFs.

(a) *No automatic renewal.* Except as provided in § 489.15(d), the term of an agreement may not be extended. The agreement shall terminate at the close of the last day of its specified term and will not be automatically renewable from term to term.

(b) *Notice of nonrenewal.* (1) If HCFA decides not to renew an agreement with a SNF, it will notify the SNF at least 30 days, and the public at least 15 days, before the end of the term.

(2) The notice will state the reasons for the determination, the effective date for the termination of the existing agreement, and the applicability of the termination to the SNF's services.

(c) *Right to hearing.* (1) The nonrenewal of an agreement under the conditions described in this section is a determination that the facility does not qualify as a provider of services for the period immediately following the term of the current agreement.

(2) The facility is entitled to a hearing as provided in Part 498 of this chapter.

[45 FR 22937, Apr. 4, 1980, as amended at 52 FR 22454, June 12, 1987]

§ 489.18 Change of ownership or leasing: Effect on provider agreement.

(a) *What constitutes change of ownership*—(1) *Partnership.* In the case of a partnership, the removal, addition, or substitution of a partner, unless the partners expressly agree otherwise, as permitted by applicable State law, constitutes change of ownership.

(2) *Unincorporated sole proprietorship.* Transfer of title and property to another party constitutes change of ownership.

(3) *Corporation.* The merger of the provider corporation into another corporation, or the consolidation of two or more corporations, resulting in the creation of a new corporation constitutes change of ownership. Transfer of corporate stock or the merger of another corporation into the provider corporation does not constitute change of ownership.

(4) *Leasing.* The lease of all or part of a provider facility constitutes change of ownership of the leased portion.

(b) *Notice to HCFA.* A provider who is contemplating or negotiating a change of ownership must notify HCFA.

(c) *Assignment of agreement.* When there is a change of ownership as specified in paragraph (a) of this section, the existing provider agreement will automatically be assigned to the new owner.

(d) *Conditions that apply to assigned agreements.* An assigned agreement is subject to all applicable statutes and regulations and to the terms and conditions under which it was originally issued including, but not limited to, the following:

(1) Any existing plan of correction.

(2) Any expiration date.

(3) Compliance with applicable health and safety standards.

(4) Compliance with the ownerhsip and financial interest disclosure requirements of Part 420, Subpart C, of this chapter.

(5) Compliance with civil rights requirements set forth in 45 CFR Parts 80, 84, and 90.

(e) *Effect of leasing.* The provider agreement will be assigned to the lessee only to the extent of the leased portion of the facility.

Subpart B—Essentials of Provider Agreements

§ 489.20 Basic commitments.

The provider agrees—

(a) To limit its charges to beneficiaries and to other individuals on their behalf, in accordance with provisions of Subpart C of this part;

(b) To comply with the requirements of Subpart D of this part for the return or other disposition of any amounts incorrectly collected from a beneficiary or any other person in his or her behalf;

(c) To comply with the requirements of § 420.203 of this chapter when it hires certain former employees of intermediaries;

(d) In the case of a hospital that furnishes inpatient hospital services to a beneficiary, to either furnish directly or make arrangements for all items and services (other than physicians' services as described in § 405.550(b) of this chapter) for which the beneficiary is entitled to have payment made under Medicare; and

(e) In the case of a hospital that furnishes inpatient hospital services for which payment may be made under Subpart D of Part 405 of this chapter, to maintain an agreement with a utilization and quality control peer review organization (if there is such an organization for the area in which the hospital is located, which has a contract with HCFA under Part B of title XI of the Act) for that organization to review the admissions, quality, appropriateness, and diagnostic information related to such inpatient hospital services.

[45 FR 22937, Apr. 4, 1980, as amended at 48 FR 39837, Sept. 1, 1983; 49 FR 323, Jan. 3, 1984]

§ 489.21 Specific limitations on charges.

Except as specified in Subpart C of this part, the provider agrees not to charge a beneficiary for any of the following:

(a) Services for which the beneficiary is entitled to have payment made under Medicare.

(b) Services for which the beneficiary would be entitled to have payment made if the provider—

(1) Had in its files the required certification and recertification by a physician relating to the services furnished to the beneficiary;

(2) Had furnished the information required by the intermediary in order to determine the amount due the provider on behalf of the individual for the period with respect to which payment is to be made or any prior period;

(3) Had complied with the provisions requiring timely utilization review of long stay cases so that a limitation on days of service has not been imposed under section 1866(d) of the Act (see Subpart K of Part 405 and Part 482 of this chapter for utilization review requirements); and

(4) Had obtained, from the beneficiary or a person acting on his or her behalf, a written request for payment to be made to the provider, and had properly filed that request. (If the beneficiary or person on his or her behalf refuses to execute a written request, the provider may charge the beneficiary for all services furnished to him or her.)

(c) Inpatient hospital services furnished to a beneficiary who exhausted his or her Part A benefits, if HCFA reimburses the provider for those services.

(d) Custodial care and services not reasonable and necessary for the diagnosis or treatment of illness or injury, if—

(1) The beneficiary was without fault in incurring the expenses; and

(2) The determination that payment was incorrect was not made until after the third year following the year in which the payment notice was sent to the beneficiary.

(e) Inpatient hospital services for which a beneficiary would be entitled to have payment made under Part A of Medicare but for a denial or reduction in payments under regulations at § 412.48 of this chapter or under section 1886(f) of the Act.

(f) Items and services furnished to a hospital inpatient (other than physicians' services as described in § 405.550(b) of this chapter or the services of an anesthetist as described in § 405.553(b)(4) of this chapter) for which Medicare payment would be made if furnished by the hospital or by other providers or suppliers under arrangements made with them by the hospital. For this purpose, a charge by another provider or supplier for such an item or service is treated as a charge by the hospital for the item or service, and is also prohibited.

(g) Items and services furnished in connection with the implantation of cardiac pacemakers or pacemaker leads when HCFA denies payment for those devices under § 409.19 or § 410.64 of this chapter.

[49 FR 324, Jan. 3, 1984, as amended at 51 FR 22052, June 17, 1986; 52 FR 27765, July 23, 1987]

§ 489.22 Special provisions applicable to prepayment requirements.

(a) A provider may not require an individual entitled to hospital insurance benefits to prepay in part or in whole for inpatient services as a condition of admittance as an inpatient, except where it is clear upon admission that payment under Medicare, Part A cannot be made.

(b) A provider may not deny covered inpatient services to an individual entitled to have payment made for those services on the ground of inability or failure to pay a requested amount at or before admission.

(c) A provider may not evict, or threaten to evict, an individual for inability to pay a deductible or a coinsurance amount required under Medicare.

(d) A provider may not charge an individual for (1) its agreement to admit or readmit the individual on some specified future date for covered inpatient services; or (2) for failure to remain an inpatient for any agreed-upon length of time or for failure to give advance notice of departure from the provider's facilities.

Subpart C—Allowable Charges

§ 489.30 Allowable charges: Deductibles and coinsurance.

(a) *Part A deductible and coinsurance.* The provider may charge the beneficiary or other person on his or her behalf:

(1) The amount of the inpatient hospital deductible or, if less, the actual charges for the services;

(2) The amount of inpatient hospital coinsurance applicable for each day the individual is furnished inpatient hospital services after the 60th day, during a benefit period; and

(3) The posthospital SNF care coinsurance amount.

(4) In the case of durable medical equipment (DME) furnished as a home health service, 20 percent of the customary charge for the service.

(b) *Part B deductible and coinsurance.* (1) The basic allowable charges are the $75 deductible and 20 percent of the customary (insofar as reasonable) charges in excess of that deductible.

(2) For hospital outpatient services, the allowable deductible charges depend on whether the hospital can determine the beneficiary's deductible status.

(i) If the hospital is unable to determine the deductible status, it may charge the beneficiary its full customary charges up to $75.

(ii) If the beneficiary provides official information as to deductible status, the hospital may charge only the unmet portion of the deductible.

(3) In either of the cases discussed in paragraph (b)(2) of this section, the hospital is required to file with the intermediary, on a form prescribed by HCFA, information as to the services, charges, and amounts collected.

(4) The intermediary must reimburse the beneficiary if reimbursement is authorized and credit the expenses to the beneficiary's deductible if the deductible has not yet been met.

(5) In the case of DME furnished as a home health service under Medicare Part B, the coinsurance is 20 percent of the customary (insofar as reasonable) charge for the services, with the following exception: If the DME is used DME purchased by or on behalf of the beneficiary at a price at least 25 percent less than the reasonable charge for comparable new equipment, no coinsurance is required.

[45 FR 22937, Apr. 4, 1980, as amended at 51 FR 41350, Nov. 14, 1986]

§ 489.31 Allowable charges: Blood.

(a) *Part A deductible.* A provider may charge the beneficiary (or other person on his or her behalf) for the first three pints of blood, or units of packed red blood cells furnished during a benefit period. Charges are subject to the following conditions:

(1) They may not exceed the provider's customary charges.

(2) No charge may be made for any whole blood or packed red cells that are replaced, pint for pint, or unit for unit, by or on behalf of the beneficiary.

(b) *Part B deductible.* (1) A provider may charge a beneficiary (or other person on his or her behalf) for the first 3 pints of whole blood or units of packed red cells furnished during a benefit period, even though a part A blood deductible has been charged during that same period.

(2) The charges are subject to the limitations specified in paragraph (a) of this section.

(c) *Excess charges.* If the charge exceeds the cost to the provider, that excess will be deducted from any Medicare payments due the provider.

§ 489.32 Allowable charges: Noncovered and partially covered services.

(a) *Services requested by beneficiary.* If services furnished at the request of a beneficiary (or his or her representative) are more expensive than, or in excess of, services covered under Medicare—

(1) A provider may charge the beneficiary an amount that does not exceed the difference between—

(i) The provider's customary charges for the services furnished; and

(ii) The provider's customary charges for the kinds and amounts of services that are covered under Medicare.

(2) A provider may not charge for the services unless they have been requested by the beneficiary (or his or her representative) nor require a beneficiary to request services as a condition of admission.

(3) To avoid misunderstanding and disputes, a provider must inform any beneficiary who requests a service for which a charge will be made that there will be a specified charge for that service.

(b) *Services not requested by the beneficiary.* For special provisions that apply when a provider customarily furnishes more expensive services, see § 413.35 of this chapter.

[45 FR 22937, Apr. 4, 1980, as amended at 51 FR 34833, Sept. 30, 1986]

§ 489.35 Notice to intermediary.

The provider must inform its intermediary of any amounts collected from a beneficiary or from other persons on his or her behalf.

Subpart D—Handling of Incorrect Collections

§ 489.40 Definition of incorrect collection.

(a) As used in this subpart, "incorrect collections" means any amounts collected from a beneficiary (or someone on his or her behalf) that are not authorized under Subpart C of this part.

(b) A payment properly made to a provider by an individual not considered entitled to Medicare benefits will be deemed to be an "incorrect collection" when the individual is found to be retroactively entitled to benefits.

§ 489.41 Timing and methods of handling.

(a) *Refund.* Prompt refund to the beneficiary or other person is the preferred method of handling incorrect collections.

(b) *Setting aside.* If the provider cannot refund within 60 days from the date on the notice of incorrect collection, it must set aside an amount, equal to the amount incorrectly collected, in a separate account identified as to the individual to whom the payment is due. This amount incorrectly collected must be carried on the provider's records in this manner until final disposition is made in accordance with the applicable State law.

(c) *Notice to, and action by, intermediary.* (1) The provider must notify the intermediary of the refund or setting aside required under paragraphs (a) and (b) of this section.

(2) If the provider fails to refund or set aside the required amounts, they may be offset against amounts otherwise due the provider.

§ 489.42 Payment of offset amounts to beneficiary or other person.

(a) In order to carry out the commitment to refund amounts incorrectly collected, HCFA may determine that amounts offset in accordance with § 489.41 are to be paid directly to the beneficiary or other person from whom the provider received the incorrect collection, if:

(1) HCFA finds that the provider has failed, following written request, to refund the amount of the incorrect collection to the beneficiary or other person; and

(2) The provider agreement has been terminated in accordance with the provisions of Subpart E of this part.

(b) Before making a determination to make payment under paragraph (a) of this section, HCFA will give written notice to the provider (1) explaining that an incorrect collection was made and the amount; (2) requesting the provider to refund the incorrect collection to the beneficiary or other person; and (3) advising of HCFA's intention to make a determination under paragraph (a) of this section.

(c) The notice will afford an authorized official of the provider an opportunity to submit, within 20 days from the date on the notice, written statement or evidence with respect to the incorrect collection and/or offset amounts. HCFA will consider any written statement or evidence in making a determination.

(d) Payment to a beneficiary or other person under the provisions of paragraph (a) of this section:

(1) Will not exceed the amount o the incorrect collection; and

(2) May be considered as paymen made to the provider.

Subpart E—Termination of Agreement and Reinstatement After Termination

§ 489.52 Termination by the provider.

(a) *Notice to HCFA.* (1) A provider that wishes to terminate its agreement must send HCFA written notice of its intent.

(2) The notice may state the intended date of termination which must be the first day of a month.

(b) *Termination date.* (1) If the notice does not specify a date, or the date is not acceptable to HCFA, HCFA may set a date that will not be more than 6 months from the date on the provider's notice of intent.

(2) HCFA may accept a termination date that is less than 6 months after the date on the provider's notice if it determines that to do so would not unduly disrupt services to the community or otherwise interfere with the effective and efficient administration of the Medicare program.

(3) A cessation of business is deemed to be a termination by the provider, effective with the date on which it stopped providing services to the community.

(c) *Public notice.* (1) The provider must give notice to the public at least 15 days before the effective date of termination.

(2) The notice must be published in one or more local newspapers and must—

(i) Specify the termination date; and

(ii) Explain to what extent services may continue after that date, in accordance with the exceptions set forth in § 489.55.

§ 489.53 Termination by HCFA.

(a) *Basis for termination of agreement with any provider.* HCFA may terminate the agreement with any provider if HCFA finds that any of the following failings is attributable to that provider:

(1) It is not complying with the provisions of title XVIII and the applicable regulations of this chapter or with the provisions of the agreement.

(2) It places restrictions on the persons it will accept for treatment and it fails either to exempt Medicare beneficiaries from those restrictions or to apply them to Medicare beneficiaries the same as to all other persons seeking care.

(3) It no longer meets the appropriate conditions of participation set forth elsewhere in this chapter.

(4) It fails to furnish information that HCFA finds necessary for a determination as to whether payments are or were due under Medicare and the amounts due.

(5) It refuses to permit examination of its fiscal or other records by, or on behalf of HCFA, as necessary for verification of information furnished as a basis for payment under Medicare.

(6) It failed to furnish information on business transactions as required in § 420.205 of this chapter.

(7) It failed at the time the agreement was entered into or renewed to disclose information on convicted individuals as required in § 420.204 of this chapter.

(8) It failed to furnish ownership information as required in § 420.206 of this chapter.

(9) It failed to comply with civil rights requirements set forth in 45 CFR Parts 80, 84, and 90.

(b) *Required termination of agreement with a SNF.* HCFA will terminate a SNF's provider agreement if it determines that—

(1) The SNF no longer meets a condition of participation specified in Part 405, Subpart K of this chapter; and

(2) The SNF's deficiencies pose immediate jeopardy to patients' health and safety.

(c) *Notice of termination*—(1) *Timing: Basic rule.* Except as provided in paragraph (c)(2) of this section, HCFA will give the provider notice of termination at least 15 days before the effective date of termination of the provider agreement.

(2) *Exception.* For a SNF with deficiencies that pose immediate jeopardy to patients' health and safety, HCFA will give notice of termination at least 2 days before the effective date of termination of the provider agreement.

(3) *Content of notice.* The notice will state the reasons for, and the effective date of, the termination, and explain the extent to which services may con-

tinue after that date, in accordance with § 489.55.

(4) *Notice to public.* HCFA will concurrently give notice of the termination to the public.

(d) *Appeal by the provider.* A provider may appeal the termination of its provider agreement by HCFA in accordance with Part 498 of this chapter.

[51 FR 24492, July 3, 1986, as amended at 52 FR 22454, June 12, 1987]

§ 489.54 Termination by the OIG.

(a) *Basis for termination.* (1) The OIG may terminate the agreement of any provider if the OIG finds that any of the following failings can be attributed to that provider.

(i) It has knowingly and willfully made, or caused to be made, any false statement or representation of a material fact for use in an application or request for payment under Medicare.

(ii) It has submitted, or caused to be submitted, requests for Medicare payment of amounts that substantially exceed the costs it incurred in furnishing the services for which payment is requested.

(iii) It has furnished services that the OIG has determined to be substantially in excess of the needs of individuals or of a quality that fails to meet professionally recognized standards of health care. The OIG will not terminate a provider agreement under paragraph (a) if HCFA has waived a disallowance with respect to the services in question on the grounds that the provider and the beneficiary could not reasonably be expected to know that payment would not be made. (The rules for determining such lack of knowledge are set forth in §§ 405.330 through 405.334 of this chapter.)

(b) *Notice of termination.* The OIG will give the provider notice of termination at least 15 days before the effective date of termination of the agreement, and will concurrently give notice of termination to the public.

(c) *Appeal by the provider.* A provider may appeal a termination of its agreement by the OIG in accordance with Subpart O of Part 405 of this chapter.

(d) *Other applicable rules.* The termination of a provider agreement by the OIG is subject to the additional procedures specified in §§ 1001.105 through 1001.109 of this title for notice and appeals.

[51 FR 24492, July 3, 1986, as amended at 51 FR 34788, Sept. 30, 1986]

§ 489.55 Exceptions to effective date of termination.

Payment is available for up to 30 days after the effective date of termination for—

(a) Inpatient hospital services (including inpatient psychiatric hospital services) and posthospital extended care services furnished to a beneficiary who was admitted before the effective date of termination; and

(b) Home health services and hospice care furnished under a plan established before the effective date of termination.[1]

[50 FR 37376, Sept. 13, 1985]

§ 489.57 Reinstatement after termination.

When a provider agreement has been terminated by HCFA under § 489.53, or by the OIG under § 489.54, a new agreement with that provider will not be accepted unless HCFA or the OIG, as appropriate, finds—

(a) That the reason for termination of the previous agreement has been removed and there is reasonable assurance that it will not recur; and

(b) That the provider has fulfilled or has made satisfactory arrangements to fulfill, all of the statutory and regulatory responsibilities of its previous agreement.

[51 FR 24493, July 3, 1986]

Subpart F—Denial of Payments to SNF's for New Admissions; Withholding of Payment

SOURCE: 51 FR 24493, July 3, 1986, unless otherwise noted.

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[1] For termination before July 18, 1984 payment was available through the calendar year in which the termination was effective.

§ 489.60 Denial of payments for new admissions.

(a) *Basis for denial of payments.* HCFA may deny Medicare payments for new admissions to an SNF that no longer meets a condition of participation specified in Subpart K of Part 405 of this chapter, in either of the following circumstances:

(1) *Deficiencies do not pose immediate jeopardy.* If HCFA finds that the SNF's deficiencies do not pose immediate jeopardy to patient health and safety, HCFA may either terminate the SNF's provider agreement or deny payment for new admissions. In determining which sanction to impose, HCFA considers factors such as the facility's compliance history and the number and seriousness of the deficiencies.

(2) *Deficiencies do pose immediate jeopardy.* If HCFA finds that the SNF's deficiencies do pose immediate jeopardy to patient health and safety, and thereby terminates the SNF's provider agreement, HCFA will additionally seek to deny payment for new admissions.

(b) *Effect of Medicare denial on an SNF that also participates in Medicaid.* When HCFA denies payment for new admissions to an SNF that also participates in Medicaid, HCFA will require the Medicaid agency to deny Medicaid payments for new admissions for the same period that Medicare payments are denied.

§ 489.62 Procedures for denial of payments.

Before denying payments for new admissions, HCFA will fulfill the following requirements.

(a) Provide the facility up to 60 days to correct the cited deficiencies and achieve compliance with the SNF conditions of participation.

(b) If at the end of the specified period the facility has not achieved compliance, give the facility notice of intent to deny payment for new admissions, and opportunity for an informal hearing.

(c) If the facility requests a hearing, provide an informal hearing that includes—

(1) The opportunity for the facility to present, before an HCFA official who was not involved in making the initial determination, evidence and documentation, in writing or in person, to refute the decision that the facility is out of compliance with the conditions of participation of standards; and

(2) A written decision setting forth the factual and legal bases pertinent to a resolution of the dispute.

(d) If the decision of the informal hearing is to deny payments for new admissions, provide the facility and the public, at least 15 days before the effective date of the sanction, with a notice that includes the effective date and the reasons for the denial of payments.

§ 489.64 Duration of denial of payments and subsequent termination.

(a) *Period of denial.* The denial of payments will continue for 11 months after the month it was imposed unless, before the end of that period, HCFA finds that—

(1) The SNF has corrected the deficiencies or is making a good faith effort to achieve compliance with the conditions of participation; or

(2) The deficiencies are such that it is necessary to terminate the provider agreement.

(b) *Subsequent termination.* HCFA will terminate an SNF's provider agreement—

(1) Upon HCFA's finding that the SNF has been unable to achieve compliance with the conditions of participation during the period of denial of payments for new admissions;

(2) Effective the day following the last day of the denial of payments period; and

(3) In accordance with the procedures for terminations and reinstatements set forth in §§ 489.53 through 489.57.

§ 489.66 Withholding of payment for failure to make timely utilization review.

(a) If HCFA finds that there is a substantial failure to make timely utilization review of long-stay cases in a hospital or skilled nursing facility, HCFA may determine that no payment shall be made for inpatient hospital services (including inpatient tuberculosis hospital services and inpatient psychiatric hospital services) or for posthospital extended care services furnished an individual after the 20th day of a continuing period of such services.

(b) Before making a determination to withhold payment, HCFA will notify the provider of its intention and will afford the institution or agency an opportunity for a hearing.

(c) The withholding of payment will become effective as of the date specified in the determination and be applicable to services furnished to individuals admitted after that date.

(d) The withholding will continue in effect until HCFA finds that:

(1) The reason for the withholding has been removed; and

(2) There is reasonable assurance that it will not recur.

[45 FR 22937, Apr. 4, 1980. Redesignated at 51 FR 24492, July 3, 1986]

PART 491—CERTIFICATION OF CERTAIN HEALTH FACILITIES

Subpart A—Rural Health Clinics: Conditions for Certification

Sec.

491.1 Purpose and scope.
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491.11 Program evaluation.

AUTHORITY: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

SOURCE: 43 FR 5375, Feb. 8, 1978, unless otherwise noted. Redesignated at 50 FR 33034, Aug. 16, 1985.

Subpart A—Rural Health Clinics: Conditions for Certification

§ 491.1 Purpose and scope.

This subpart sets forth the conditions that rural health clinics must meet in order to qualify for reimbursement under Medicare (Title XVIII of the Social Security Act) and Medicaid (Title XIX of the Act).

§ 491.2 Definitions.

As used in this subpart, unless the context indicates otherwise:

(a) "Direct services " means services provided by the clinic's staff.

(b) "Nurse practitioner " means a registered professional nurse who is currently licensed to practice in the State, who meets the State's requirements governing the qualifications of nurse practitioners, and who meets one of the following conditions:

(1) Is currently certified as a primary care nurse practitioner by the American Nurses' Association or by the National Board of Pediatric Nurse Practitioners and Associates; or

(2) Has satisfactorily completed a formal 1 academic year educational program that:

(i) Prepares registered nurses to perform an expanded role in the delivery of primary care;

(ii) Includes at least 4 months (in the aggregate) of classroom instruction and a component of supervised clinical practice; and

(iii) Awards a degree, diploma, or certificate to persons who successfully complete the program; or

(3) Has successfully completed a formal educational program (for preparing registered nurses to perform an expanded role in the delivery of primary care) that does not meet the requirements of paragraph (b)(2) of this section, and has been performing an expanded role in the delivery of primary care for a total of 12 months during the 18-month period immediately preceding the effective date of this subpart.

(c) "Physician" means a doctor of medicine or osteopathy legally authorized to practice medicine or surgery in the State.

(d) "Physician assistant" means a person who meets the applicable State requirements governing the qualifications for assistants to primary care physicians, and who meets at least one of the following conditions:

(1) Is currently certified by the National Commission on Certification of

Physician Assistants to assist primary care physicians; or

(2) Has satisfactorily completed a program for preparing physician's assistants that:

(i) Was at least 1 academic year in length;

(ii) Consisted of supervised clinical practice and at least 4 months (in the aggregate) of classroom instruction directed toward preparing students to deliver health care; and

(iii) Was accredited by the American Medical Association's Committee on Allied Health Education and Accreditation; or

(3) Has satisfactorily completed a formal educational program (for preparing physician assistants) that does not meet the requirements of paragraph (d)(2) of this section and has been assisting primary care physicians for a total of 12 months during the 18-month period immediately preceding the effective date of this subpart.

(e) "Rural area" means an area that is not delineated as an urbanized area by the Bureau of the Census.

(f) "Rural health clinic" or "clinic" means a clinic that is located in a rural area designated as a shortage area, is not a rehabilitation agency or a facility primarily for the care and treatment of mental diseases, and meets all other requirements of this subpart.

(g) "Shortage area" means a defined geographic area designated by the Department as having either a shortage of personal health services (under section 1302(7) of the Public Health Service Act) or a shortage of primary medical care manpower (under section 332 of that Act).

(h) "Secretary" means the Secretary of Health and Human Services, or any official to whom he has delegated the pertinent authority.

(Secs. 1102, 1833 and 1902(a)(13), Social Security Act: 49 Stat. 647, 91 Stat. 1485 (42 U.S.C. 1302, 1395l and 1396(a)(13)))

[43 FR 5375, Feb. 8, 1978, as amended at 43 FR 30528, July 14, 1978. Redesignated at 50 FR 33034, Aug. 16, 1985]

§ 491.3 Certification procedures.

A rural health clinic will be certified for participation in Medicare in accordance with Subpart S of 42 CFR Part 405. The Secretary will notify the State Medicaid agency whenever he has certified or denied certification under Medicare for a prospective rural health clinic in that State. A clinic certified under Medicare will be deemed to meet the standards for certification under Medicaid.

§ 491.4 Compliance with Federal, State and local laws.

The rural health clinic and its staff are in compliance with applicable Federal, State and local laws and regulations.

(a) *Licensure of clinic.* The clinic is licensed pursuant to applicable State and local law.

(b) *Licensure, certification or registration of personnel.* Staff of the clinic are licensed, certified or registered in accordance with applicable State and local laws.

§ 491.5 Location of clinic.

(a) *Basic requirement.* The clinic is located in a rural area that is designated as a shortage area, and may be a permanent or a mobile unit.

(1) *Permanent unit.* The objects, equipment and supplies necessary for the provision of the services furnished directly by the clinic are housed in a permanent structure.

(2) *Mobile unit.* The objects, equipment, and supplies necessary for the provision of the services furnished directly by the clinic are housed in a mobile structure which has fixed, scheduled location(s).

Under this requirement, if clinic services are furnished at permanent units in more than one location, each unit will be independently considered for certification as a rural health clinic.

(b) *Exceptions.* (1) A facility certified under this subpart will not be disqualified if the area in which it is located subsequently fails to meet the definition of rural, shortage area.

(2) A private, nonprofit facility that meets all other conditions of this subpart except for location in a shortage area will be certified if, on July 1, 1977, it was operating in a rural area that is determined by the Secretary (on the basis of the ratio of primary care physicians to the general population) to have an insufficient supply of

physicians to meet the needs of the area served.

(3) Determinations on these exceptions will be made by the Secretary upon application by the facility.

(c) *Criteria for designation of rural areas.* (1) Rural areas are areas not delineated as urbanized areas in the last census conducted by the Census Bureau.

(2) Excluded from the rural area classification are:

(i) Central cities of 50,000 inhabitants or more;

(ii) Cities with at least 25,000 inhabitants which, together with contiguous areas having stipulated population density, have combined populations of 50,000 and constitute, for general economic and social purposes, single communities;

(iii) Closely settled territories surrounding cities and specifically designated by the Census Bureau as urban.

(3) Included in the rural area classification are those portions of extended cities that the Census Bureau has determined to be rural.

(d) *Criteria for designation of shortage areas.* (1) The criteria for determination of shortage of personal health services (under section 1302(7) of the Public Health Services Act), are:

(i) The ratio of primary care physicians practicing within the area to the resident population;

(ii) The infant mortality rate;

(iii) The percent of the population 65 years of age or older; and

(iv) The percent of the population with a family income below the poverty level.

(2) The criteria for determination of shortage of primary medical care manpower (under section 332(a)(1)(A) of the Public Health Services Act) are:

(i) The area served is a rational area for the delivery of primary medical care services;

(ii) The ratio of primary care physicians practicing within the area to the resident population; and

(iii) The primary medical care manpower in contiguous areas is overutilized, excessively distant, or inaccessible to the population in this area.

CROSS REFERENCE: See 42 CFR 110.203(g) (41 FR 45718, Oct. 15, 1976) and 42 CFR Part 5 (42 FR 1586, Jan. 10, 1978).

§ 491.6 Physical plant and environment.

(a) *Construction.* The clinic is constructed, arranged, and maintained to insure access to and safety of patients, and provides adequate space for the provision of direct services.

(b) *Maintenance.* The clinic has a preventive maintenance program to ensure that:

(1) All essential mechanical, electrical and patient-care equipment is maintained in safe operating condition;

(2) Drugs and biologicals are appropriately stored; and

(3) The premises are clean and orderly.

(c) *Emergency procedures.* The clinic assures the safety of patients in case of non-medical emergencies by:

(1) Training staff in handling emergencies;

(2) Placing exit signs in appropriate locations; and

(3) Taking other appropriate measures that are consistent with the particular conditions of the area in which the clinic is located.

§ 491.7 Organizational structure.

(a) *Basic requirements.* (1) The clinic is under the medical direction of a physician, and has a health care staff that meets the requirements of § 491.8.

(2) The organization's policies and its lines of authority and responsibilities are clearly set forth in writing.

(b) *Disclosure.* The clinic discloses the names and addresses of:

(1) Its owners, in accordance with section 1124 of the Social Security Act (42 U.S.C. 132 A-3);

(2) The person principally responsible for directing the operation of the clinic; and

(3) The person responsible for medical direction.

§ 491.8 Staffing and staff responsibilities.

(a) *Staffing.* (1) The clinic has a health care staff that includes one or more physicians and one or more physician's assistants or nurse practitioners.

(2) The physician member of the staff may be the owner of the clinic, an employee of the clinic, or under

agreement with the clinic to carry out the responsibilities required under this section.

(3) The physician's assistant or nurse practitioner member of the staff may be the owner of the clinic or an employee of the clinic.

(4) The staff may also include ancillary personnel who are supervised by the professional staff.

(5) The staff is sufficient to provide the services essential to the operation of the clinic.

(6) A physician, nurse practitioner, or physician assistant is available to furnish patient care services at all times the clinic operates. A nurse practitioner or a physician assistant is available to furnish patient care services at least 60 percent of the time the clinic operates.

(b) *Physician responsibilities.* (1) The physician:

(i) Provides medical direction for the clinic's health care activities and consultation for, and medical supervision of, the health care staff.

(ii) In conjunction with the physician's assistant and/or nurse practitioner member(s), participates in developing, executing, and periodically reviewing the clinic's written policies and the services provided to Federal program patients; and

(iii) Periodically reviews the clinic's patient records, provides medical orders, and provides medical care services to the patients of the clinic.

(2) A physician is present for sufficient periods of time, at least once in every 2 week period (except in extraordinary circumstances), to provide the medical direction, medical care services, consultation and supervision described in paragraph (b)(1) of this section, and is available through direct telecommunication for consultation, assistance with medical emergencies, or patient referral. The extraordinary circumstances are documented in the records of the clinic.

(c) *Physician assistant and nurse practitioner responsibilities.* (1) The physician assistant and the nurse practitioner members of the clinic's staff:

(i) Participate in the development, execution and periodic review of the written policies governing the services the clinic furnishes;

(ii) Participate with a physician in a periodic review of the patients' health records.

(2) The physician assistant or nurse practitioner performs the following functions, to the extent they are not being performed by a physician:

(i) Provides services in accordance with the clinic's policies;

(ii) Arranges for, or refers patients to, needed services that cannot be provided at the clinic; and

(iii) Assures that adequate patient health records are maintained and transferred as required when patients are referred.

(Secs. 1102, 1833, and 1902(a)(13), Social Security Act: 49 Stat. 647, 91 Stat. 1485 (42 U.S.C. 1302, 1395l and 1396a(a)(13)))

[43 FR 5375, Feb. 8, 1978, as amended at 43 FR 30528, July 14, 1978. Redesignated at 50 FR 33034, Aug. 16, 1985]

§ 491.9 Provision of services.

(a) *Basic requirements.* (1) All services offered by the clinic are furnished in accordance with applicable Federal, State, and local laws; and (2) the clinic is primarily engaged in providing outpatient health services meets all other conditions of this subpart.

(b) *Patient care policies.* (1) The clinic's health care services are furnished in accordance with appropriate written policies which are consistent with applicable State law.

(2) The policies are developed with the advice of a group of professional personnel that includes one or more physicians and one or more physician assistants or nurse practitioners. At least one member is not a member of the clinic staff.

(3) The policies include:

(i) A description of the services the clinic furnishes directly and those furnished through agreement or arrangement.

(ii) Guidelines for the medical management of health problems which include the conditions requiring medical consultation and/or patient referral, the maintenance of health care records, and procedures for the periodic review and evaluation of the services furnished by the clinic.

(iii) Rules for the storage, handling, and administration of drugs and biologicals.

(4) These policies are reviewed at least annually by the group of professional personnel required under paragraph (b)(2) of this section, and reviewed as necessary by the clinic.

(c) *Direct services*—(1) *General.* The clinic staff furnishes those diagnostic and therapeutic services and supplies that are commonly furnished in a physician's office or at the entry point into the health care delivery system. These include medical history, physical examination, assessment of health status, and treatment for a variety of medical conditions.

(2) *Laboratory.* The clinic provides basic laboratory services essential to the immediate diagnosis and treatment of the patient, including:

(i) Chemical examinations of urine by stick or tablet methods or both (including urine ketones);

(ii) Microscopic examinations of urine sediment;

(iii) Hemoglobin or hematacrit;

(iv) Blood sugar;

(v) Gram stain;

(vi) Examination of stool specimens for occult blood;

(vii) Pregnancy tests;

(viii) Primary culturing for transmittal to a certified laboratory; and

(ix) Test for pinworm.

(3) *Emergency.* The clinic provides medical emergency procedures as a first response to common life-threatening injuries and acute illness, and has available the drugs and biologicals commonly used in life saving procedures, such as analgesics, anesthetics (local), antibiotics, anticonvulsants, antidotes and emetics, serums and toxoids.

(d) *Services provided through agreements or arrangements.* (1) The clinic has agreements or arrangements with one or more providers or suppliers participating under Medicare or Medicaid to furnish other services to its patients, including:

(i) Inpatient hospital care;

(ii) Physician(s) services (whether furnished in the hospital, the office, the patient's home, a skilled nursing facility, or elsewhere); and

(iii) Additional and specialized diagnostic and laboratory services that are not available at the clinic.

(2) If the agreements are not in writing, there is evidence that patients referred by the clinic are being accepted and treated.

(Secs. 1102, 1833, and 1902(a)(13), Social Security Act: 49 Stat. 647, 91 Stat. 1485 (42 U.S.C. 1302, 1395l and 1396a(a)(13)))

[43 FR 5375, Feb. 8, 1978, as amended at 43 FR 30528, July 14, 1978. Redesignated at 50 FR 33034, Aug. 16, 1985]

§ 491.10 Patient health records.

(a) *Records system.* (1) The clinic maintains a clinical record system in accordance with written policies and procedures.

(2) A designated member of the professional staff is responsible for maintaining the records and for insuring that they are completely and accurately documented, readily accessible, and systematically organized.

(3) For each patient receiving health care services, the clinic maintains a record that includes, as applicable:

(i) Identification and social data, evidence of consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient;

(ii) Reports of physical examinations, diagnostic and laboratory test results, and consultative findings;

(iii) All physician's orders, reports of treatments and medications, and other pertinent information necessary to monitor the patient's progress;

(iv) Signatures of the physician or other health care professional.

(b) *Protection of record information.* (1) The clinic maintains the confidentiality of record information and provides safeguards against loss, destruction or unauthorized use.

(2) Written policies and procedures govern the use and removal of records from the clinic and the conditions for release of information.

(3) The patient's written consent is required for release of information not authorized by law.

(c) *Retention of records.* The records are retained for at least 6 years from date of last entry, and longer if required by State statute.

(Secs. 1102, 1833 and 1902(a)(13), Social Security Act; 49 Stat. 647, 91 Stat. 1485 (42 U.S.C. 1302, 1395l and 1396a(a)(13)))

[43 FR 30529, July 14, 1978. Redesignated at 50 FR 33034, Aug. 16, 1985]

§ 491.11 Program evaluation.

(a) The clinic carries out, or arranges for, an annual evaluation of its total program.

(b) The evaluation includes review of:

(1) The utilization of clinic services, including at least the number of patients served and the volume of services;

(2) A representative sample of both active and closed clinical records; and

(3) The clinic's health care policies.

(c) The purpose of the evaluation is to determine whether:

(1) The utilization of services was appropriate;

(2) The established policies were followed; and

(3) Any changes are needed.

(d) The clinic staff considers the findings of the evaluation and takes corrective action if necessary.

PART 498—APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM

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AUTHORITY: Secs. 205(a), 1102, 1869(c) 1871, and 1872 of the Social Security Act (42 U.S.C. 405(a), 1302, 1395ff(c), 1395hh and 1395ii), unless otherwise noted.

SOURCE: 52 FR 22446, June 12, 1987, unless otherwise noted.

Subpart A—General Provisions

§ 498.1 Statutory basis.

(a) Section 1869(c) of the Act provides for a hearing and for judicial review of the hearing for any institution or agency dissatisfied with a determination that it is not a provider, or with any determination described in section 1866(b)(2) of the Act.

(b) Section 1866(b)(2) of the Act lists determinations that serve as a basis for termination of a provider agreement.

(c) Section 1128 (a) and (b) of the Act provide for exclusion of certain individuals or entities because of conviction of crimes related to their participation in Medicare.

(d) Section 1156 of the Act establishes certain obligations for practitioners and providers of health care services, and provides sanctions and penalties for those that fail to meet those obligations.

(e) Section 1862(d) of the Act provides for the exclusion of individuals or entities that submit false claims, bill excessive charges or furnish substandard care.

(f) HFCA is responsible for implementing section 1869(c) of the Act, and section 1866 (b)(2), except subparagraphs (D), (E), and (F). The OIG is responsible for implementing the other cited sections.

(g) Although sections 1866 and 1869 of the Act are silent regarding appeal rights for suppliers and practitioners, the rules in this part include procedures for review of determinations that affect those two groups.

§ 498.2 Definitions.

As used in this part—

Affected party means a provider, prospective provider, supplier, prospective supplier, or practitioner that is affected by an initial determination or by any subsequent determination or decision issued under this part, and "party" means the affected party or HCFA (or the OIG), as appropriate.

ALJ stands for Administrative Law Judge.

Appeals Council or *Council* means the Appeals Council of the Office of Hearings and Appeals of the Social Security Administration.

OHA stands for the Social Security Administration's Office of Hearings and Appeals.

OIG stands for the Department's Office of the Inspector General.

Provider means a hospital, skilled nursing facility (SNF), comprehensive outpatient rehabilitation facility (CORF), home health agency (HHA), or hospice, that has in effect an agreement to participate in Medicare, or a clinic, rehabilitation agency, or public health agency that has a similar agreement but only to furnish outpatient physical therapy or outpatient speech pathology services, and "*prospective provider*" means any of the listed entities that seeks to participate in Medicare as a provider.

Supplier means an independent laboratory, supplier of portable X-ray services, rural health clinic (RHC), ambulatory surgical center (ASC), organ procurement organization (OPO), or end-stage renal disease (ESRD) treatment facility that is approved by HCFA as meeting the conditions for coverage of its services, and

Prospective supplier means any of the listed entities that seeks to be approved for coverage of its services under Medicare. However, for purposes of the sanctions and penalties that may be imposed by the OIG, the term "supplier" has the meaning specified in § 1001.2 of this title.

[52 FR 22446, June 12, 1987, as amended at 53 FR 6551, March 1, 1988]

§ 498.3 Scope and applicability.

(a) *Scope.* This part sets forth procedures for reviewing initial determinations that HCFA makes with respect to the matters specified in paragraph (b) of this section and that the OIG makes with respect to matters specified in paragraph (c) of this section.

(b) *Initial determinations by HCFA.* HCFA makes initial determinations with respect to the following matters:

(1) Whether a prospective provider qualifies as a provider.

(2) Whether an institution is a hospital qualified to elect to claim payment for all emergency hospital services furnished in a calendar year.

(3) Whether an institution continues to remain in compliance with the qualifications for claiming reimbursement for all emergency services furnished in a calendar year.

(4) Whether a prospective supplier meets the appropriate conditions for coverage of its services, as set forth in Part 405 (Subpart M, N, Q, or U), Part 416, Part 485, Subpart D, or Part 491 of this chapter).

(5) Whether the services of a supplier continue to meet the conditions for coverage.

(6) Whether a physical therapist in independent practice or a chiropractor meets the requirements for coverage of his or her services as set forth in §§ 405.1730 through 405.1737 or in § 410.22 of this chapter, respectively.

(7) The termination of a provider agreement in accordance with § 489.53 of this chapter, or the termination of a rural health clinic agreement in accordance with § 405.2404 of this chapter.

(8) The cancellation of the approval of a Medicaid SNF or ICF by HCFA under section 1910(c) of the Act.

(9) Whether, for purposes of rate setting and reimbursement, an ESRD treatment facility is considered to be hospital-based or independent.

(10) Whether to deny payment under § 409.10 or § 409.64 of this chapter, pertaining to cardiac pacemakers and the pacemaker registry.

(c) *Initial determinations by the OIG.* The OIG makes initial determinations with respect to the following matters:

(1) The termination of a provider agreement in accordance with Part 1001, Subpart C of this title.

(2) The suspension, or exclusion from coverage and the denial of reimbursement for services furnished by a provider, practitioner, or supplier, because of fraud or abuse, or conviction of crimes related to participation in the program, in accordance with Part 1001, Subpart B of this title.

(3) The imposition of sanctions in accordance with Part 1004 of this title.

(d) *Administrative actions that are not initial determinations.* Administrative actions other than those specified in paragraphs (b) and (c) of this section are not initial determinations and thus are not subject to this part. Administrative actions that are not initial determinations include, but are not limited to, the following:

(1) The finding that a provider or supplier determined to be in compliance with the conditions of participation or the conditions for coverage has deficiencies.

(2) The finding that a prospective provider does not meet the conditions of participation set forth in Part 405 (Subpart K, L, or Q), Part 482 or Part 485 of this chapter, if the prospective provider is, nevertheless, approved for participation in Medicare on the basis of special access certification, as provided in Subpart S of Part 405 of this chapter.

(3) The refusal to enter into a provider agreement because the prospective provider has been adjudged insolvent or bankrupt under Federal or State law, or insolvency or bankruptcy proceedings are pending.

(4) The finding that an entity that had its provider agreement terminated may not file another agreement because the reasons for terminating the previous agreement have not been removed or there is insufficient assurance that the reasons for the exclusion will not recur.

(5) The determination not to reinstate a suspended or excluded practitioner, provider, or supplier because the reason for the suspension or exclusion has not been removed, or there is insufficient assurance that the reason will not recur.

(6) The finding that the services of a laboratory are covered as hospital services or as physician's services, rather than as services of an independent laboratory, because the laboratory is not independent of the hospital or of the physician's office.

(7) The refusal to accept for filing an election to claim payment for all emergency hospital services furnished in a calendar year because the institution—

(i) Had previously charged an individual or other person for services furnished during that calendar year;

(ii) Submitted the election after the close of that calendar year; or

(iii) Had previously been notified of its failure to continue to comply.

(8) The finding that the reason for the revocation of a supplier's right to accept assignment has not been removed or there is insufficient assurance that the reason will not recur.

(9) The finding that a hospital accredited by the Joint Commission on Accreditation of Hospitals or the American Osteopathic Association is not in compliance with a condition of participation, and a finding that that hospital is no longer deemed to meet the conditions of participation.

(10) With respect to a SNF that is not in compliance with a condition of participation—

(i) The finding that the SNF's deficiencies pose immediate jeopardy to patients' health and safety; and

(ii) When the SNF's deficiencies do not pose immediate jeopardy, the decision to deny payment for new admissions.

(e) *Exclusion of civil rights issues.* The procedures in this subpart do not apply to the adjudication of issues relating to a provider's compliance with civil rights requirements that are set forth in Part 489 of this chapter. Those issues are handled through the Department's Office of Civil Rights.

[52 FR 22446, June 12, 1987, as amended at 52 FR 27765, July 23, 1987; 53 FR 6551, March 1, 1988; 53 FR 6649, March 2, 1988]

§ 498.5 Appeal rights.

(a) *Appeal rights of prospective providers.* (1) Any prospective provider dissatisfied with an initial determination or revised initial determination that it does not qualify as a provider may request reconsideration in accordance with § 498.22(a).

(2) Any prospective provider dissatisfied with a reconsidered determination under paragraph (a)(1) of this section, or a revised reconsidered determination under § 498.30, is entitled to a hearing before an ALJ.

(b) *Appeal rights of providers.* Any provider dissatisfied with an initial determination to terminate its provider agreement is entitled to a hearing before an ALJ.

(c) *Appeal rights of providers and prospective providers.* Any provider or prospective provider dissatisfied with a hearing decision may request Appeals Council review and has a right to seek judicial review of the Council's decision.

(d) *Appeal rights of prospective suppliers.* (1) Any prospective supplier dissatisfied with an initial determination or a revised initial determination that its services do not meet the conditions for coverage may request reconsideration in accordance with § 498.22(a).

(2) Any prospective supplier dissatisfied with a reconsidered determination under paragraph (d)(1) of this section, or a revised reconsidered determination under § 498.30, is entitled to a hearing before an ALJ.

(e) *Appeal rights of suppliers.* Any supplier dissatisfied with an initial determination that the services subject to the determination no longer meet the conditions for coverage, is entitled to a hearing before an ALJ.

(f) *Appeal rights of suppliers and prospective suppliers.* (1) Any supplier or prospective supplier dissatisfied with the hearing decision may request Appeals Council review of the ALJ's decision.

(2) Suppliers and prospective suppliers do not have a right to judicial review except as provided in paragraph (i) of this section.

(g) *Appeal rights for certain practitioners.* A physical therapist in independent practice or a chiropractor dissatisfied with a determination that he or she does not meet the requirements for coverage of his or her services has the same appeal rights as suppliers have under paragraphs (d), (e) and (f) of this section.

(h) *Appeal rights for nonparticipating hospitals that furnish emergency services.* A nonparticipating hospital dissatisfied with a determination or decision that it does not qualify to elect to claim payment for all emergency services furnished during a calendar year has the same appeal rights that providers have under paragraph (a), (b), and (c) of this section.

(i) *Appeal rights for suspended or excluded practitioners, providers, or suppliers.* (1) Any practitioner, provider, or supplier who has been suspended, or whose services have been excluded from coverage in accordance with § 498.3(c)(2), or has been sanctioned in accordance with § 498.3(c)(3), is entitled to a hearing before an ALJ.

(2) Any suspended or excluded practitioner, provider, or supplier dissatisfied with a hearing decision may request Appeals Council review and has a right to seek judicial review of the Council's decision by filing an action in Federal district court.

(j) *Appeal rights for Medicaid SNFs and ICFs terminated by HCFA.* (1) Any Medicaid SNF or ICF that has had its approval cancelled by HCFA in accordance with § 498.3(b)(8) has a right to a hearing before an ALJ, to request Appeals Council review of the hearing decision, and to seek judicial review of the Council's decision.

(2) The Medicaid agreement remains in effect until the period for requesting a hearing has expired or, if the facility requests a hearing, until a hearing decision is issued, unless HCFA—

(i) Makes a written determination that continuation of provider status for the SNF or ICF constitutes an immediate and serious threat to the health and safety of patients and specifies the reasons for that determination; and

(ii) Certifies that the facility has been notified of its deficiencies and has failed to correct them.

§ 498.10 Appointment of representatives.

(a) An affected party may appoint as its representative anyone not disqualified or suspended from acting as a representative in proceedings before the Secretary or otherwise prohibited by law.

(b) If the representative appointed is not an attorney, the party must file written notice of the appointment with HCFA, the ALJ, or the Appeals Council.

(c) If the representative appointed is an attorney, the attorney's statement that he or she has the authority to represent the party is sufficient.

§ 498.11 Authority of representatives.

(a) A representative appointed and qualified in accordance with § 498.10 may, on behalf of the represented party—

(1) Give and accept any notice or request pertinent to the proceedings set forth in this part;

(2) Present evidence and allegations as to facts and law in any proceedings affecting that party to the same extent as the party; and

(3) Obtain information to the same extent as the party.

(b) A notice or request may be sent to the affected party, to the party's representative, or to both. A notice or request sent to the representative has the same force and effect as if it had been sent to the party.

§ 498.13 Fees for services of representatives.

Fees for any services performed on behalf of an affected party by an attorney appointed and qualified in accordance with § 498.10 are not subject to the provisions of section 206 of Title II of the Act, which authorizes the Secretary to specify or limit those fees.

§ 498.15 Charge for transcripts.

A party that requests a transcript of prehearing or hearing proceedings or Council review must pay the actual or estimated cost of preparing the transcript unless, for good cause shown by that party, the payment is waived by the ALJ or the Appeals Council, as appropriate.

§ 498.17 Filing of briefs with the ALJ or Appeals Council, and opportunity for rebuttal.

(a) *Filing of briefs and related documents.* If a party files a brief or related document such as a written argument, contention, suggested finding of fact, conclusion of law, or any other written statement, it must submit an original and one copy to the ALJ or the Appeals Council, as appropriate. The material may be filed by mail or in person and must include a statement certifying that a copy has been furnished to the other party.

(b) *Opportunity for rebuttal.* (1) The other party will have 20 days from the date of mailing or personal service to submit any rebuttal statement or additional evidence. If a party submits a rebuttal statement or additional evidence, it must file an original and one copy with the ALJ or the Council and furnish a copy to the other party.

(2) The ALJ or the council will grant an opportunity to reply to the rebuttal statement only if the party shows good cause.

Subpart B—Initial, Reconsidered, and Revised Determinations

§ 498.20 Notice and effect of initial determinations.

(a) *Notice of initial determination*—(1) *General rule.* HCFA or the OIG, as appropriate, mails notice of an initial determination to the affected party, setting forth the basis or reasons for the determination, the effect of the determination, and the party's right to reconsideration, if applicable, or to a hearing.

(2) *Special rules: Independent laboratories and suppliers of portable x-ray services.* If HCFA determines that an independent laboratory or a supplier of portable x-ray services no longer meets the conditions for coverage of some or all of its services, the notice—

(i) Specifies an effective date of termination of coverage that is at least 15 days after the date of the notice;

(ii) Is also sent to physicians, hospitals, and other parties that might use the services of the laboratory or supplier; and

(iii) In the case of laboratories, specifies the categories of laboratory tests that are no longer covered.

(3) *Special rules: Nonparticipating hospitals that elect to claim payment for emergency services.* If HCFA determines that a nonparticipating hospital no longer qualifies to elect to claim payment for all emergency services furnished in a calendar year, the notice—

(i) States the calendar year to which the determination applies;

(ii) Specifies an effective date that is at least 5 days after the date of the notice; and

(iii) Specifies that the determination applies to services furnished, in the specified calendar year, to patients accepted (as inpatients or outpatients) on or after the effective date of the determination.

(4) *Other special rules.* Additional rules pertaining, for example, to content and timing of notice, notice to the public and to other entities, and time allowed for submittal of additional information, are set forth elsewhere in this chapter, as follows:

Part 405 Subpart X—for rural health clinics.
Part 416—for ambulatory surgical centers.
Part 489—for providers, when their provider agreements have been terminated.
Part 1001, Subpart B—for excluded or suspended providers, suppliers, physicians, or practitioners.
Part 1001, Subpart C—for providers, when their provider agreements are terminated by the OIG.
Part 1004—for sanctioned providers and practitioners.

(b) *Effect of initial determination.* An initial determination is binding unless it is—

(1) Reconsidered in accordance with § 498.24;

(2) Reversed or modified by a hearing decision in accordance with § 498.78; or

(3) Revised in accordance with § 498.32 or § 498.100.

§ 498.22 Reconsideration.

(a) *Right to reconsideration.* HCFA reconsiders any initial determination that affects a prospective provider or supplier, or a hospital seeking to qualify to claim payment for all emergency hospital services furnished in a calendar year, if the affected party files a written request in accordance with paragraphs (b) and (c) of this section. (None of the determinations made by the OIG are subject to reconsideration.)

(b) *Request for reconsideration: Manner and timing.* The affected party specified in paragraph (a) of this section, if dissatisfied with the initial determination may request reconsideration by filing the request—

(1) With HCFA or with the State survey agency;

(2) Directly or through its legal representative or other authorized official; and

(3) Within 60 days from receipt of the notice of initial determination, unless the time is extended in accordance with paragraph (d) of this section. The date of receipt will be presumed to be 5 days after the date on the notice unless there is a showing that it was, in fact, received earlier or later.

(c) *Content of request.* The request for reconsideration must state the issues, or the findings of fact with which the affected party disagrees, and the reasons for disagreement.

(d) *Extension of time to file a request for reconsideration.* (1) If the affected party is unable to file the request within the 60 days specified in paragraph (b) of this section, it may file a written request with HCFA, stating the reasons why the request was not filed timely.

(2) HCFA will extend the time for filing a request for reconsideration if the affected party shows good cause for missing the deadline.

§ 498.23 Withdrawal of request for reconsideration.

A request for reconsideration is considered withdrawn if the requestor files a written withdrawal request before HCFA mails the notice of reconsidered determination, and HCFA approves the withdrawal request.

§ 498.24 Reconsidered determination.

When a request for reconsideration has been properly filed in accordance with § 498.22, HCFA—

(a) Receives written evidence and statements that are relevant and material to the matters at issue and are submitted within a reasonable time after the request for reconsideration;

(b) Considers the initial determination, the findings on which the initial determination was based, the evidence considered in making the initial determination, and any other written evidence submitted under paragraph (a) of this section, taking into account facts relating to the status of the prospective provider or supplier subsequent to the initial determination; and

(c) Makes a reconsidered determination, affirming or modifying the initial determination and the findings on which it was based.

§ 498.25 Notice and effect of reconsidered determination.

(a) *Notice.* (1) HCFA mails notice of a reconsidered determination to the affected party.

(2) The notice gives the reasons for the determination.

(3) If the determination is adverse, the notice specifies the conditions or requirements of law or regulations that the affected party fails to meet, and informs the party of its right to a hearing.

(b) *Effect.* A reconsidered determination is binding unless—

(1) HCFA or the OIG, as appropriate, further revises the revised determination; or

(2) The revised determination is reversed or modified by a hearing decision.

Subpart C—Reopening of Initial or Reconsidered Determinations

§ 498.30 Limitation on reopening.

An initial or reconsidered determination that a prospective provider is a provider or that a hospital qualifies to elect to claim payment for all emergency services furnished in a calendar year may not be reopened. HCFA or the OIG, as appropriate, may on its own initiative, reopen any other initial or reconsidered determination, within 12 months after the date of notice of the initial determination.

§ 498.32 Notice and effect of reopening and revision.

(a) *Notice.* (1) HCFA or the OIG, as appropriate, gives the affected party notice of reopening and of any revision of the reopened determination.

(2) The notice of revised determination states the basis or reason for the revised determination.

(3) If the determination is that a supplier or prospective supplier does not meet the conditions for coverage of its services, the notice specifies the conditions with respect to which the affected party fails to meet the requirements of law and regulations, and informs the party of its right to a hearing.

(b) *Effect.* A revised determination is binding unless

(1) The affected party requests a hearing before an ALJ; or

(2) HCFA or the OIG further revises the revised determination.

Subpart D—Hearings

§ 498.40 Request for hearing.

(a) *Manner and timing of request.* (1) An affected party entitled to a hearing under § 498.5 may file a request for a hearing with HCFA or the OIG, as appropriate, or with OHA.

(2) The affected party or its legal representative or other authorized official must file the request in writing within 60 days from receipt of the notice of initial, reconsidered, or revised determination unless that period is extended in accordance with paragraph (c) of this section. (Presumed date of receipt is determined in accordance with § 498.22(b)(3)).

(b) *Content of request for hearing.* The request for hearing must—

(1) Identify the specific issues, and the findings of fact and conclusions of law with which the affected party disagrees; and

(2) Specify the basis for contending that the findings and conclusions are incorrect.

(c) *Extension of time for filing a request for hearing.* If the request was not filed within 60 days—

(1) The affected party or its legal representative or other authorized official may file with the ALJ a written request for extension of time stating the reasons why the request was not filed timely.

(2) For good cause shown, the ALJ may extend the time for filing the request for hearing.

§ 498.42 Parties to the hearing.

The parties to the hearing are the affected party and HCFA or the OIG, as appropriate.

§ 498.44 Designation of hearing official.

(a) The Associate Commissioner for Hearings and Appeals, or his or her delegate designates an ALJ or a member or members of the Appeals Council to conduct the hearing.

(b) If appropriate, the Associate Commissioner or the delegate may substitute another ALJ or another member or other members of the Appeals Council to conduct the hearing.

(c) As used in this part, "ALJ" includes a member or members of the Appeals Council who are designated to conduct a hearing.

§ 498.45 Disqualification of Administrative Law Judge.

(a) An ALJ may not conduct a hearing in a case in which he or she is prejudiced or partial to the affected party or has any interest in the matter pending for decision.

(b) A party that objects to the ALJ designated to conduct the hearing must give notice of its objections at the earliest opportunity.

(c) The ALJ will consider the objections and decide whether to withdraw or proceed with the hearing.

(1) If the ALJ withdraws, another will be designated to conduct the hearing.

(2) If the ALJ does not withdraw, the objecting party may, after the hearing, present its objections to the Appeals Council as reasons for changing, modifying, or reversing the ALJ's decision or providing a new hearing before another ALJ.

§ 498.47 Prehearing conference.

(a) At any time before the hearing, the ALJ may call a prehearing conference for the purpose of delineating the issues in controversy, identifying the evidence and witnesses to be presented at the hearing, and obtaining stipulations accordingly.

(b) On the request of either party or on his or her own motion, the ALJ may adjourn the prehearing conference and reconvene at a later date.

§ 498.48 Notice of prehearing conference.

(a) *Timing of notice.* The ALJ will fix a time and place for the prehearing conference and mail written notice to the parties at least 10 days before the scheduled date.

(b) *Content of notice.* The notice will inform the parties of the purpose of the conference and specify what issues are sought to be resolved, agreed to, or excluded.

(c) *Additional issues.* Issues other than those set forth in the notice of determination or the request for hearing may be considered at the prehearing conference if—

(1) Either party gives timely notice to that effect to the ALJ and the other party; or

(2) The ALJ raises the issues in the notice of prehearing conference or at the conference.

§ 498.49 Conduct of prehearing conference.

(a) The prehearing conference is open to the affected party or its representative, to the HCFA or OIG representatives and their technical advisors, and to any other persons whose presence the ALJ considers necessary or proper.

(b) The ALJ may accept the agreement of the parties as to the following:

(1) Facts that are not in controversy.

(2) Questions that have been resolved favorably to the affected party after the determination in dispute.

(3) Remaining issues to be resolved.

(c) The ALJ may request the parties to indicate the following:

(1) The witnesses that will be present to testify at the hearing.

(2) The qualifications of those witnesses.

(3) The nature of other evidence to be submitted.

§ 498.50 Record, order, and effect of prehearing conference.

(a) *Record of prehearing conference.* (1) A record is made of all agreements and stipulations entered into at the prehearing conference.

(2) The record may be transcribed at the request of either party or the ALJ.

(b) *Order and opportunity to object.* (1) The ALJ issues an order setting forth the results of the prehearing conference, including the agreements made by the parties as to facts not in controversy, the matters to be considered at the hearing, and the issues to be resolved.

(2) Copies of the order are sent to all parties and the parties have 10 days to file objections to the order.

(3) After the 10 days have elapsed, the ALJ settles the order.

(c) *Effect of prehearing conference.* The agreements and stipulations entered into at the prehearing conference are binding on all parties, unless a party presents facts that, in the opinion of the ALJ, would make an agreement unreasonable or inequitable.

§ 498.52 Time and place of hearing.

(a) The ALJ fixes a time and place for the hearing and gives the parties written notice at least 10 days before the scheduled date.

(b) The notice informs the parties of the general and specific issues to be resolved at the hearing.

§ 498.53 Change in time and place of hearing.

(a) The ALJ may change the time and place for the hearing either on his or her own initiative or at the request of a party for good cause shown, or may adjourn or postpone the hearing.

(b) The ALJ may reopen the hearing for receipt of new evidence at any time before mailing the notice of hearing decision.

(c) The ALJ gives the parties reasonable notice of any change in time or place or any adjournment or reopening of the hearing.

§ 498.54 Joint hearings.

When two or more affected parties have requested hearings and the same or substantially similar matters are at issue, the ALJ may, if all parties agree, fix a single time and place for the prehearing conference or hearing and conduct all proceedings jointly. If joint hearings are held, a single record of the preceedings is made and a separate decision issued with respect to each affected party.

§ 498.56 Hearing on new issues.

(a) *Basic rules.* (1) Within the time limits specified in paragraph (b) of this section, the ALJ may, at the request of either party, or on his or her own motion, provide a hearing on new issues that impinge on the rights of the affected party.

(2) The ALJ may consider new issues even if HCFA or the OIG has not made initial or reconsidered determinations on them, and even if they arose after the request for hearing was filed or after a prehearing conference.

(3) The ALJ may give notice of hearing on new issues at any time after the hearing request is filed and before the hearing record is closed.

(b) *Time limits.* The ALJ will not consider any issue that arose on or after any of the following dates:

(1) The effective date of the termination of a provider agreement.

(2) The date on which it is determined that a supplier no longer meets the conditions for coverage of its services.

(3) The effective date of the notice to a hospital of its failure to remain in compliance with the qualifications for claiming reimbursement for all emergency services furnished to Medicare beneficiaries during the calendar year.

(4) The effective date of the suspension, or of the exclusion from coverage of services furnished by a suspended or excluded practitioner, provider, or supplier.

(5) With respect to Medicaid SNFs or ICFs surveyed under section 1910(c) of the Act—

(i) The completion date of the survey or resurvey that is the basis for a proposed cancellation of approval; or

(ii) If approval was cancelled before the hearings, because of immediate and serious threat to patient health and safety, the effective date of cancellation.

(c) *Notice and conduct of hearing on new issues.* (1) Unless the affected party waives its right to appear and present evidence, notice of the time and place of hearing on any new issue will be given to the parties in accordance with § 498.52.

(2) After giving notice, the ALJ will, except as provided in paragraph (d) of this section, proceed to hearing on new issues in the same manner as on an issue raised in the request for hearing.

(d) *Remand to HCFA or the OIG.* At the request of either party, or on his or her own motion, in lieu of a hearing under paragraph (c) of this section, the ALJ may remand the case to HCFA or the OIG for consideration of the new issue and, if appropriate, a determination. If necessary, the ALJ may direct HCFA or the OIG to return the case to the ALJ for further proceedings.

[52 FR 22446, June 12, 1987, as amended at 53 FR 31335, Aug. 18, 1988]

§ 498.58 Subpoenas.

(a) *Basis for issuance.* The ALJ, upon his or her own motion or at the request of a party, may issue subpoenas if they are reasonably necessary for the full presentation of a case.

(b) *Timing of request by a party.* The party must file a written request for a subpoena with the ALJ at least 5 days before the date set for the hearing.

(c) *Content of request.* The request must:

(1) Identify the witnesses or documents to be produced;

(2) Describe their addresses or location with sufficient particularity to permit them to be found; and

(3) Specify the pertinent facts the party expects to establish by the witnesses or documents, and indicate why those facts could not be established without use of a subpoena.

(d) *Method of issuance.* Subpoenas are issued in the name of the Secretary, who pays the cost of issuance and the fees and mileage of any subpoenaed witnesses.

§ 498.60 Conduct of hearing.

(a) *Participants in the hearing.* The hearing is open to the parties and their representatives and technical advisors, and to any other persons whose presence the ALJ considers necessary or proper.

(b) *Hearing procedures.* (1) The ALJ inquires fully into all of the matters at issue, and receives in evidence the testimony of witnesses and any documents that are relevant and material.

(2) If the ALJ believes that there is relevant and material evidence available which has not been presented at the hearing, he may, at any time before mailing of notice of the decision, reopen the hearing to receive that evidence.

(3) The ALJ decides the order in which the evidence and the arguments of the parties are presented and the conduct of the hearing.

§ 498.61 Evidence.

Evidence may be received at the hearing even though inadmissible under the rules of evidence applicable to court procedure. The ALJ rules on the admissibility of evidence.

§ 498.62 Witnesses.

Witnesses at the hearing testify under oath or affirmation. The representative of each party is permitted to examine his or her own witnesses subject to interrogation by the representative of the other party. The ALJ may ask any questions that he or she deems necessary. The ALJ rules upon any objection made by either party as to the propriety of any question.

§ 498.63 Oral and written summation.

The parties to a hearing are allowed a reasonable time to present oral summation and to file briefs or other written statements of proposed findings of fact and conclusions of law. Copies of any briefs or other written statements must be sent in accordance with § 498.17.

§ 498.64 Record of hearing.

A complete record of the proceedings at the hearing is made and transcribed in all cases.

§ 498.66 Waiver of right to appear and present evidence.

(a) *Waiver procedures.* (1) If an affected party wishes to waive its right to appear and present evidence at the hearing, it must file a written waiver with the ALJ.

(2) If the affected party wishes to withdraw a waiver, it may do so, for good cause, at any time before the ALJ mails notice of the hearing decision.

(b) *Effect of waiver.* If the affected party waives the right to appear and present evidence, the ALJ need not conduct an oral hearing except in one of the following circumstances:

(1) The ALJ believes that the testimony of the affected party or its representatives or other witnesses is necessary to clarify the facts at issue.

(2) HCFA or the OIG shows good cause for requiring the presentation of oral evidence.

(c) *Dismissal for failure to appear.* If, despite the waiver, the ALJ sends notice of hearing and the affected party fails to appear, or to show good cause for the failure, the ALJ will dismiss the appeal in accordance with § 498.69.

(d) *Hearing without oral testimony.* When there is no oral testimony, the ALJ will—

(1) Make a record of the relevant written evidence that was considered in making the determination being appealed, and of any additional evidence submitted by the parties;

(2) Furnish to each party copies of the additional evidence submitted by the other party; and

(3) Give both parties a reasonable opportunity for rebuttal.

(e) *Handling of briefs and related statements.* If the parties submit briefs or other written statements of evidence or proposed findings of facts or conclusions of law, those documents will be handled in accordance with § 498.17.

§ 498.68 Dismissal of request for hearing.

(a) The ALJ may, at any time before mailing the notice of the decision, dismiss a hearing request if a party withdraws its request for a hearing or the affected party asks that its request be dismissed.

(b) An affected party may request a dismissal by filing a written notice with the ALJ.

§ 498.69 Dismissal for abandonment.

(a) The ALJ may dismiss a request for hearing if it is abandoned by the party that requested it.

(b) The ALJ may consider a request for hearing to be abandoned if the party or its representative—

(1) Fails to appear at the prehearing conference or hearing without having previously shown good cause for not appearing; and

(2) Fails to respond, within 10 days after the ALJ sends a "show cause" notice, with a showing of good cause.

§ 498.70 Dismissal for cause.

On his or her own motion, or on the motion of a party to the hearing, the ALJ may dismiss a hearing request either entirely or as to any stated issue, under any of the following circumstances:

(a) *Res judicata.* There has been a previous determination or decision with respect to the rights of the same affected party on the same facts and law pertinent to the same issue or issues which has become final either by judicial affirmance or, without judicial consideration, because the affected party did not timely request reconsideration, hearing, or review, or commence a civil action with respect to that determination or decision.

(b) *No right to hearing.* The party requesting a hearing is not a proper party or does not otherwise have a right to a hearing.

(c) *Hearing request not timely filed.* The affected party did not file a hearing request timely and the time for filing has not been extended.

§ 498.71 Notice and effect of dismissal and right to request review.

(a) Notice of the ALJ's dismissal action is mailed to the parties. The notice advises the affected party of its right to request that the dismissal be vacated as provided in § 498.72.

(b) The dismissal of a request for hearing is binding unless it is vacated by the ALJ or the Appeals Council.

§ 498.72 Vacating a dismissal of request for hearing.

An ALJ may vacate any dismissal of a request for hearing if a party files a request to that effect within 60 days from receipt of the notice of dismissal and shows good cause for vacating the dismissal. (Date of receipt is determined in accordance with § 498.22(b)(3).)

§ 498.74 Administrative Law Judge's decision.

(a) *Timing, basis and content.* As soon as practical after the close of the hearing, the ALJ issues a written decision in the case. The decision is based on the evidence of record and contains separate numbered findings of fact and conclusions of law.

(b) *Notice and effect.* A copy of the decision is mailed to the parties and is binding on them unless—

(1) A party requests review by the Appeals Council within the stated time period, and the Council reviews the case;

(2) The Appeals Council denies the request for review and the party seeks judicial review by filing an action in a Federal district court;

(3) The decision is revised by an ALJ or the Appeals Council; or

(4) The decision is a recommended decision directed to the Council.

§ 498.76 Removal of hearing to Appeals Council.

(a) At any time before the ALJ receives oral testimony, the Council may remove to itself any pending request for a hearing.

(b) Notice of removal is mailed to each party.

(c) The Council conducts the hearing in accordance with the rules that apply to ALJ hearings under this subpart.

§ 498.78 Remand by the Administrative Law Judge.

(a) If HCFA or the OIG requests remand, and the affected party concurs in writing or on the record, the ALJ may remand any case properly before him or her to HCFA or the OIG for a determination satisfactory to the affected party.

(b) The ALJ may remand at any time before notice of hearing decision is mailed.

Subpart E—Appeals Council Review

§ 498.80 Right to request Appeals Council review of Administrative Law Judge's decision or dismissal.

Either of the parties has a right to request Appeals Council review of the

ALJ's decision or dismissal order, and the parties are so informed in the notice of the ALJ's action.

§ 498.82 Request for Appeals Council review.

(a) *Manner and time of filing.* (1) Any party that is dissatisfied with an ALJ's decision or dismissal of a hearing request, may file a written request for review by the Appeals Council.

(2) The requesting party or its representative or other authorized official must file the request with the OHA within 60 days from receipt of the notice of decision or dismissal, unless the Council, for good cause shown by the requesting party, extends the time for filing. The rules set forth in § 498.40(c) apply to extension of time for requesting Appeals Council review. (The date of receipt of notice is determined in accordance with § 498.22(c)(3).)

(b) *Content of request for review.* A request for review of an ALJ decision or dismissal must specify the issues, the findings of fact or conclusions of law with which the party disagrees, and the basis for contending that the findings and conclusions are incorrect.

§ 498.83 Appeals Council action on request for review.

(a) *Request by HCFA or the OIG.* The Appeals Council may dismiss, deny, or grant a request made by HCFA or the OIG for review of an ALJ decision or dismissal.

(b) *Request by the affected party.* The Council will grant the affected party's request for review unless it dismisses the request for one of the following reasons:

(1) The affected party requests dismissal of its request for review.

(2) The affected party did not file timely or show good cause for late filing.

(3) The affected party does not have a right to review.

(4) A previous determination or decision, based on the same facts and law, and regarding the same issue, has become final through judicial affirmance or because the affected party failed to timely request reconsideration, hearing, Council review, or judicial review, as appropriate.

(c) *Effect of dismissal.* The dismissal of a request for Appeals Council review is binding and not subject to further review.

(d) *Review panel.* If the Council grants a request for review of the ALJ's decision, the review will be conducted by a panel of at least two members of the Council, designated by the Chairperson or Deputy Chairperson, and one individual designated by the Secretary from the U.S Public Health Service.

§ 498.85 Procedures before the Appeals Council on review.

The parties are given, upon request, a reasonable opportunity to file briefs or other written statements as to fact and law, and to appear before the Appeals Council to present evidence or oral arguments. Copies of any brief or other written statement must be sent in accordance with § 498.17.

§ 498.86 Evidence admissible on review.

(a) The Appeals Council may admit evidence into the record in addition to the evidence introduced at the ALJ hearing, (or the documents considered by the ALJ if the hearing was waived), if the Council considers that the additional evidence is relevant and material to an issue before it.

(b) If it appears to the Council that additional relevant evidence is available, the Council will require that it be produced.

(c) Before additional evidence is admitted into the record—

(1) Notice is mailed to the parties (unless they have waived notice) stating that evidence will be received regarding specified issues; and

(2) The parties are given a reasonable time to comment and to present other evidence pertinent to the specified issues.

(d) If additional evidence is presented orally to the Council, a transcript is prepared and made available to any party upon request.

§ 498.88 Decision or remand by the Appeals Council.

(a) When the Appeals Council reviews an ALJ's decision or order of dismissal, or receives a case remanded by a court, the Council may either issue a decision or remand the case to an ALJ for a hearing and decision or a recommended decision for final decision by the Council.

(b) In a remanded case, the ALJ initiates additional proceedings and takes other actions as directed by the Council in its order of remand, and may take other action not inconsistent with that order.

(c) Upon completion of all action called for by the remand order and any other consistent action, the ALJ promptly makes a decision or, as specified by the Council, certifies the case to the Council with a recommended decision.

(d) The parties have 20 days from the date of a notice of a recommended decision to submit to the Council any exception, objection, or comment on the findings of fact, conclusions of law, and recommended decision.

(e) After the 20-day period, the Council issues its decision adopting, modifying or rejecting the ALJ's recommended decision.

(f) If the Council does not remand the case to an ALJ, the following rules apply:

(1) The Council's decision—

(i) Is based upon the evidence in the hearing record and any further evidence that the Council receives during its review;

(ii) Is in writing and contains separate numbered findings of fact and conclusions of law; and

(iii) May modify, affirm, or reverse the ALJ's decision.

(2) A copy of the Council's decision is mailed to each party.

§ 498.90 Effect of Appeals Council decision.

(a) The decision of the Appeals Council is binding unless—

(1) The affected party has a right to judicial review and timely files a civil action in a district court of the United States; or

(2) The Council reopens and revises its decision in accordance with § 498.102.

(b) Section 498.5 specifies the circumstances under which an affected party has a right to seek judicial review.

§ 498.95 Extension of time for seeking judicial review.

(a) Any affected party that is dissatisfied with an Appeals Council decision and is entitled to judicial review must commence civil action within 60 days from receipt of the notice of the Council's decision (as determined under § 498.22(c)(3)), unless the Council extends the time in accordance with paragraph (c) of this section.

(b) The request for extension must be filed in writing with the Council before the 60-day period ends.

(c) For good cause shown, the Council may extend the time for commencing civil action.

Subpart F—Reopening of Decisions Made by Administrative Law Judges or the Appeals Council

§ 498.100 Basis, timing, and authority for reopening an ALJ or Council decision.

(a) *Basis and timing for reopening.* An ALJ of Appeals Council decision may be reopened, within 60 days from the date of the notice of decision, upon the motion of the ALJ or the Council or upon the petition of either party to the hearing.

(b) *Authority to reopen.* (1) A decision of the Appeals Council may be reopened only by the Appeals Council.

(2) A decision of an ALJ may be reopened by that ALJ, by another ALJ if that one is not available, or by the Appeals Council. For purposes of this paragraph, an ALJ is considered to be unavailable if the ALJ has died, terminated employment, or been transferred to another duty station, is on leave of absence, or is unable to conduct a hearing because of illness.

§ 498.102 Revision of reopened decision.

(a) *Revision based on new evidence.* If a reopened decision is to be revised on the basis of new evidence that was not included in the record of that decision, the ALJ or the Appeals Council—

(1) Notifies the parties of the proposed revision; and

(2) Unless the parties waive their right to hearing or appearance—

(i) Grants a hearing in the case of a ALJ revision; and

(ii) Grants opportunity to appear in the case of a Council revision.

(b) *Basis for revised decision and right to review.* (1) If a revised decision is necessary, the ALJ or the Appeals Council, as appropriate, renders it on the basis of the entire record.

(2) If the decision is revised by an ALJ, the Appeals Council may review that revised decision at the request of either party or on its own motion.

§ 498.103 Notice and effect of revised decision.

(a) *Notice.* The notice mailed to the parties states the basis or reason for the revised decision and informs them of their right to Appeals Council review of an ALJ revised decision, or to judicial review of a Council reviewed decision.

(b) *Effect*—(1) *ALJ revised decision.* An ALJ revised decision is binding unless it is reviewed by the Appeals Council.

(2) *Appeals Council revised decision.* A Council revised decision is binding unless a party files a civil action in a district court of the United States within the time frames specified in § 498.95.

CHAPTER V—OFFICE OF INSPECTOR GENERAL—HEALTH CARE, DEPARTMENT OF HEALTH AND HUMAN SERVICES

SUBCHAPTER A—GENERAL PROVISIONS

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SUBCHAPTER A—GENERAL PROVISIONS

PART 1000—INTRODUCTION; GENERAL DEFINITIONS

Subpart A—[Reserved]

Subpart B—Definitions

Sec.
1000.10 General definitions.
1000.20 Definitions specific to Medicare.
1000.30 Definitions specific to Medicaid.

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 51 FR 34766, Sept. 30, 1986, unless otherwise noted.

Subpart A—[Reserved]

Subpart B—Definitions

§ 1000.10 General definitions.

In this chapter, unless the context indicates otherwise—

Act means the Social Security Act, and titles referred to are titles of that Act.

Administrator means the Administrator, Health Care Financing Administration.

CFR stands for Code of Federal Regulations.

Department means the Department of Health and Human Services (HHS), formerly the Department of Health, Education, and Welfare.

ESRD stands for end-stage renal disease.

FR stands for *Federal Register*.

HCFA stands for Health Care Financing Administration.

HHS stands for the Department of Health and Human Services.

HHA stands for home health agency.

HMO stands for health maintenance organization.

ICF stands for intermediate care facility.

Inspector General means the Inspector General for Health and Human Services.

Medicaid means medical assistance provided under a State plan approved under Title XIX of the Act.

Medicare means the health insurance program for the aged and disabled under Title XVIII of the Act.

OIG means the Office of Inspector General within HHS.

PRO stands for Utilization and Quality Control Peer Review Organization.

Secretary means the Secretary of Health and Human Services.

SNF stands for skilled nursing facility.

Social security benefits means monthly cash benefits payable under section 202 or 223 of the Act.

SSA stands for Social Security Administration.

United States means the fifty States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

U.S.C. stands for United States Code.

§ 1000.20 Definitions specific to Medicare.

As used in connection with the Medicare program, unless the context indicates otherwise—

Beneficiary means a person who is entitled to Medicare benefits.

Carrier means an entity that has a contract with HCFA to determine and make Medicare payments for Part B benefits payable on a charge basis and to perform other related functions.

Entitled means that an individual meets all the requirements for Medicare benefits.

Hospital insurance benefits means payments on behalf of, and in rare circumstances directly to, an entitled individual for services that are covered under Part A of Title XVIII of the Act.

Intermediary means an entity that has a contract with HCFA to determine and make Medicare payments for Part A or Part B benefits payable on a cost basis and to perform other related functions.

Medicare Part A means the hospit insurance program authorized unde Part A of Title XVIII of the Act.

Medicare Part B means the supp mentary medical insurance progra authorized under Part B of Ti XVIII of the Act.

Provider means a hospital, a skill nursing facility, a comprehensive o patient rehabilitation facility, a home health agency, or effective November 1, 1983 through September 30, 1986, a hospice that has in effect an agreement to participate in Medicare, or a clinic, a rehabilitation agency, or a public health agency that has a similar agreement but only to furnish outpatient physical therapy or speech pathology services.

Railroad retirement benefits means monthly benefits payable to individuals under the Railroad Retirement Act of 1974 (45 U.S.C. beginning at section 231).

Services means medical care or services and items, such as medical diagnosis and treatment, drugs and biologicals, supplies, appliances, and equipment, medical social services, and use of hospital or SNF facilities.

Supplementary medical insurance benefits means payment to or on behalf of an entitled individual for services covered under Part B of Title XVIII of the Act.

Supplier means a physician or other practitioner, or an entity other than a provider, that furnishes health care services under Medicare.

§ 1000.30 Definitions specific to Medicaid.

As used in connection with the Medicaid program, unless the context indicates otherwise—

Applicant means an individual whose written application for Medicaid has been submitted to the agency determining Medicaid eligibility, but has not received final action. This includes an individual (who need not be alive at the time of application) whose application is submitted through a representative or a person acting responsibly for the individual.

Federal financial participation (FFP) means the Federal Government's share of a State's expenditures under the Medicaid program.

FMAP stands for the Federal medical assistance percentage, which is used to calculate the amount of Federal share of State expenditures for services.

Medicaid agency or *agency* means the single State agency administering or supervising the administration of a State Medicaid plan.

Provider means any individual or entity furnishing Medicaid services under a provider agreement with the Medicaid agency.

Recipient means an individual who has been determined eligible for Medicaid.

Services means the types of medical assistance specified in sections 1905(a)(1) through (18) of the Act.

State means the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa and the Northern Mariana Islands.

State plan or *the plan* means a comprehensive written commitment by a Medicaid agency, submitted under section 1902(a) of the Act, to administer or supervise the administration of a Medicaid program in accordance with Federal requirements.

SUBCHAPTER B—OIG AUTHORITIES

PART 1001—PROGRAM INTEGRITY: MEDICARE

Subpart A—General Provisions

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1001.2 Definitions.
1001.3 Applicability of other regulations.

Subpart B—Suspension, Exclusion, or Termination of Practitioners, Providers, Suppliers of Services, and Other Individuals

1001.100 Basis and scope.

SUSPENSIONS, EXCLUSIONS OR TERMINATION ON BASIS OF FRAUD OR ABUSE

1001.101 Bases for exclusion for fraud or abuse; exceptions.
1001.102 Sanctions for violations of the freeze on physician charges.
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SUSPENSIONS ON BASIS OF CONVICTION OF PROGRAM-RELATED CRIME

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Subpart C—Termination of Agreement and Reinstatement After Termination

1001.201 Termination by the OIG.
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Subpart D—Payment Denial Under the Prospective Payment System

1001.301 Denial of payment as a result of admissions and quality review.

AUTHORITY: Secs. 1102, 1128, 1842(j), 1842(k), 1862(d), 1862(e), 1866(b)(2)(D), (E) and (F), and 1871 of the Social Security Act (42 U.S.C. 1302, 1320a-7, 1395u(j), 1395u(k), 1395y(d), 1395y(e), 1395cc(b)(2)(D), (E) and (F), and 1395hh), unless otherwise noted.

SOURCE: 51 FR 34767, Sept. 30, 1986, unless otherwise noted.

Subpart A—General Provisions

§ 1001.1 Scope and purpose.

This part sets forth provisions for the detection and prevention of fraud and abuse in the Medicare program. It implements statutory sections, specifically identified in each subpart, aimed at protecting the integrity of the Medicare program.

§ 1001.2 Definitions.

Convicted means that a judgment of conviction has been entered by a Federal, State, or local court, regardless of whether an appeal from that judgment is pending.

Exclusion means that items or services furnished by a specified practitioner, provider, or other supplier of services will not be reimbursed under Medicare.

Furnished refers to items and services provided directly by, or under the direct supervision of, or ordered by, a practitioner or other individual (either as an employee or in his or her own capacity), a provider, or other supplier of services. (For purposes of denial of reimbursement within this part, it does not refer to services ordered by one party but billed for and provided by or under the supervision of another.)

HHS means Department of Health and Human Services.

OIG means Office of Inspector General of the Department of Health and Human Services.

Practitioner means a physician or other individual licensed under State law to practice his or her profession.

PRO means Utilization and Quality Control Peer Review Organization as created by the Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. 97-248.

Provider means (a) hospital, a skilled nursing facility, a comprehensive outpatient rehabilitation facility, a home health agency, or a hospice that has in effect an agreement to participate in Medicare, Medicaid, or the social services programs, or (b) a clinic, a rehabilitation agency, or a public health agency that has a similar agreement, but only to furnish outpatient physical therapy or speech pathology services.

Supplier or *supplier of services* means an individual or entity, other than a provider or practitioner, that furnishes health care services under Medicare, Medicaid, or the social services programs.

Suspension means that items or services furnished by a specified party who has been convicted of a program related offense in a Federal, State, or local court will not be reimbursed under Medicare or Medicaid.

§ 1001.3 Applicability of other regulations.

Part 498 of this title contains detailed procedures for hearings and reviews that are made available under this part for exclusions and terminations on the basis of fraud and abuse. Appeal procedures applicable to suspension based on a conviction for a program-related crime are specified in § 1001.128 of this part.

[51 FR 34767, Sept. 30, 1986, as amended at 52 FR 22454, June 12, 1987]

Subpart B—Suspension, Exclusion, or Termination of Practitioners, Providers, Suppliers of Services, and Other Individuals

§ 1001.100 Basis and scope.

This subpart implements sections 1128, 1842(j), 1842(k) and 1862(d) and (e) of the Act. It sets forth criteria and procedures for—

(a) Excluding (1) practitioners, providers, and suppliers of services who have defrauded or abused the Medicare program, (2) Physicians who have violated the billing restrictions of section 1842(k) of the Act by billing for services performed by, or as, an assistant at cataract surgery, or (3) For those physician practitioners who are not participating physicians, who have violated the billing restrictions of section 1842(j) of the Act, and

(b) For suspending practitioners and other individuals convicted of crimes related to their participation in the delivery of medical care or services under the Medicare, Medicaid or the social services programs.

[52 FR 11651, Apr. 10, 1987]

SUSPENSIONS, EXCLUSIONS OR TERMINATION ON BASIS OF FRAUD OR ABUSE

§ 1001.101 Bases for exclusions for fraud or abuse; exceptions.

(a) Payment will not be made under Medicare for items or services furnished by a practitioner, provider, or other supplier of services that the OIG determines has;

(1) Knowingly and willfully made or caused to be made any false statement or misrepresentation of a material fact in a request for payment under Medicare or for use in determining the right to payment under Medicare.

(2) Furnished items or services that are substantially in excess of the beneficiary's needs or of a quality that does not meet professionally recognized standards of health care; or

(3) Submitted or caused to be submitted bills or requests for payment containing charges (or costs) that are substantially in excess of its customary charges (or costs).

(b) The OIG's determination under paragraph (a)(2) of this section, that the items or services furnished were excessive or of unacceptable quality, will be made on the basis of reports, including sanction reports, from the following sources:

(1) The PSRO or PRO for the area served by the practitioner, provider, or other supplier of services;

(2) State or local licensing or certification authorities;

(3) Peer review committees of fiscal agents or contractors;

(4) State or local professional societies; or

(5) Other sources deemed appropriate by the OIG.

(c) *Exceptions.* (1) Notwithstanding the circumstances specified in paragraph (a)(2) of this section, HCFA will not deny Medicare payments if it has waived a disallowance on the grounds that the beneficiary and the practitioner, provider, or other supplier of services could not reasonably be expected to know that payment would not be made for a particular item or service (See § 405.330 of this title.)

(2) HCFA will not deny Medicare payment for bills or requests that are substantially in excess of customary charges or costs, if it finds the excess changes are justified by unusual circumstances or medical complications requiring additional time, effort, or expense in localities in which it is accepted medical practice to make an extra charge in such case.

§ 1001.102 Sanctions for violations of the freeze on physician charges.

(a) Whenever the OIG determines that a physician, who is not a participating physician under section 1842(h) of the Act, has during the statutory period of the freeze (1) provided services to a beneficiary and (2) knowingly and willfully billed that beneficiary for actual charges that are in excess of the physician's actual charges for the calendar quarter beginning on April 1, 1984, the OIG may exclude the physician from program participation for a period of up to five years, impose a monetary penalty or assessment against the physician, or both.

(b) If the OIG makes a determination under paragraph (a) of this section that involves a monetary penalty or assessment, the OIG will use the penalty determination, notification, effectuation, and appeal procedures contained in §§ 1003.100 through 1003.130 of this chapter.

(c) If the OIG makes a determination under paragraph (a) of this section and proposes to exclude a physician from Medicare program participation without imposing a monetary penalty or assessment, the OIG will use the determination, notification, effectuation, appeal, and reinstatement procedures contained in §§ 1001.100 through 1001.115 and 1001.130 through 1001.134.

§ 1001.103 Exclusion for violations of the freeze on physician charges.

(a) In excluding a physician under § 1001.102, the exclusion period determined under § 1001.114 may not exceed five years.

(b) The OIG will not impose an exclusion under § 1001.102 if it determines that the physician is the sole source of essential specialized service or a sole community physician.

§ 1001.104 Sanctions and exclusion for the billing for charges of services by or as an assistant at surgery during cataract operations.

(a) Whenever the OIG determines that—

(1) A physician knowingly and willfully bills for charges of services as an assistant at surgery during a routine cataract operation, or includes in his or her bill the services of an assistant at surgery during a routine cataract operation, and

(2) Prior approval for use of such an assistant has not been obtained from the appropriate Peer Review Organization or Medicare carrier, the OIG may exclude either one or both physicians from program participation for a period of up to five years, impose a civil monetary penalty against the physician (or physicians), or both [For cataract operations performed during the period April 1, 1986 to December 15, 1986, a carrier will be deemed to have approved the use of an assistant at surgery before the surgery was performed if the carrier determined, after the operation, that the use of such an assistant was approp

ate based on a complicating medical condition before or during the surgery.]

(b) If the OIG makes a determination under paragraph (a) of this section that involves a civil monetary penalty, the OIG will use the penalty determination, notification, effectuation, and appeal procedures contained in §§ 1003.100 through 1003.130 of this chapter.

(c)(1) If the OIG makes a determination under paragraph (a) of this section and proposes to exclude a physician, or physicians, from Medicare program participation without imposing a civil monetary penalty, the OIG will use the determination, notification, effectuation, appeal, and reinstatement procedures contained in §§ 1001.100 through 1001.115 and §§ 1001.130 through 1001.134.

(2) In excluding a physician, or physicians, under paragraph (a) of this section, the exclusion period determined under § 1001.114 may not exceed five years.

[52 FR 11651, Apr. 10, 1987]

§ 1001.105 Notice of proposed exclusion or termination for fraud or abuse.

(a) If the OIG proposes to deny reimbursement in accordance with § 1001.101, or to terminate a provider agreement in accordance with § 1001.201(a) (1), (2), or (3) of this chapter, it will send written notice of its intent and the reasons for the proposed exclusion or termination to the practitioner, provider or other supplier of services.

(b) Within 30 days of the date on the notice, the party may submit:

(1) Documentary evidence and written argument against the proposed action; or

(2) A written request to present evidence or argument orally to an OIG official.

(c) For good cause shown by the party, the OIG may extend the 30-day period.

§ 1001.107 Notice of exclusion or termination to affected party.

(a) If, after a party has exhausted the procedures specified in § 1001.105, the OIG decides to exclude the party under § 1001.101 or to terminate a provider agreement under § 1001.201(a) (1), (2), or (3) it will send written notice of its decision to the affected party at least 15 days before the decision becomes effective.

(b) The notice will state

(1) The reasons for the decision;

(2) The effective date;

(3) The extent of its applicability to participation in the Medicare program;

(4) The earliest date on which the OIG will accept a request for reinstatement;

(5) The requirements and procedures for reinstatement; and

(6) The appeal rights available to the excluded party.

(c) This decision and notice constitute an "initial determination" and a "notice of initial determination" for purposes of the administrative appeals procedures specified in Subpart O of Part 405 of this title.

§ 1001.109 Notice to others regarding exclusion or termination.

Notice of exclusion or termination and the effective date will also be given to the public and, as appropriate, to:

(a) State Medicaid and title V agencies, State Medicaid Fraud Control Units, and PROs.

(b) Hospitals, skilled nursing facilities, home health agencies and health maintenance organizations (HMOs);

(c) Medical societies and other professional organizations;

(d) Contractors, health care prepayment plans and other affected agencies and organizations; and

(e) The State or local authority responsible for licensing or certifying the excluded party.

§ 1001.114 Duration of exclusion.

(a) The exclusion of a petitioner, provider, or other supplier of services will continue until the party is reinstated in accordance with §§ 1001.130 through 1001.136.

(b) The exclusion notice will specify the earliest date on which the excluded party may seek reinstatement. In setting that date, the OIG will consider:

(1) The number and nature of the program violations and other related offenses:

(2) The nature and extent of any adverse impact the violations have had on beneficiaries:

(3) The amount of any damages incurred by the Medicare program:

(4) Whether there are any mitigating circumstances:

(5) Any other facts bearing on the nature and seriousness of the violations or related offenses; and

(6) The previous sanction record of the excluded party under the Medicare or Medicaid program.

(c) For the effective date of termination of a provider agreement under § 1001.201(a) (1), (2), or (3), see § 1001.201(b) of this chapter.

§ 1001.115 Effect of exclusion.

(a) *Denial of payments during exclusion.* (1) Except as provided in paragraph (c) of this section, payment will not be made to an excluded practitioner, provider, or other supplier of services (that has accepted assignment of beneficiary claims), for items or services furnished on or after the effective date of exclusion specified in the exclusion notice.

(2) An assignment of a beneficiary's claim that is made on or after the effective date of exclusion will not be valid.

(b) *Denial of payment to beneficiaries.* If a beneficiary submits claims for items or services furnished by an excluded practitioner, provider, or other supplier of services after the effective date of the exclusion:

(1) HCFA will pay the first claim submitted by the beneficiary and immediately give notice of the exclusion.

(2) HCFA will not pay the beneficiary for items or services furnished by an excluded party more than 15 days after the date on the notice to the beneficiary or after the effective date of the exclusion, whichever is later.

(c) *Exceptions.* Payment is available for up to 30 days after the effective date of exclusion for—

(1) Inpatient hospital services (including inpatient psychiatric hospital services) or posthospital extended care services furnished to a beneficiary who was admitted before the effective date of exclusion; and

(2) Home health services and hospice care furnished under a plan established before the effective date of exclusion.

SUSPENSIONS ON BASIS OF CONVICTION OF PROGRAM-RELATED CRIME

§ 1001.122 Bases for suspension for conviction of program-related crime and individuals affected.

(a) The OIG will suspend from participation in Medicare any party specified in paragraph (b) of this section who is convicted on or after October 25, 1977, of a criminal offense related to—

(1) Participation in the delivery of medical care or services under the Medicare, Medicaid, or the social services program; or

(2) Participation in the performance of management or administrative services relating to delivery of medical care or services under the Medicare, Medicaid, or the social services program.

(b) The suspension from participation in Medicare for conviction of a program-related crime, specified in paragraph (a) of this section, will apply to—

(1) Practitioners;

(2) Suppliers that are wholly owned by a convicted individual;

(3) Individuals who are employees, administrators, or operators of providers; and

(4) Any other individuals who, in any capacity, are receiving payments for providing services under Medicare, Medicaid, or the social services programs.

(c) The OIG will also require the State Medicaid agency to suspend any convicted party specified in paragraphs (a) and (b) of this section whether or not that party is eligible to participate in the Medicare program.

§ 1001.123 Notice to affected party of suspension for conviction of program-related crime.

(a) Whenever the OIG has conclusive information that a practitioner or other individual has been convicted of a crime related to his or her partic tion in the delivery of medical care or services under the Medicare, Medicaid, or the social services program, it will give the party written notice that he or she is suspended from participation in Medicare beginning 15 days from the date on the notice. In the case of a party who is not eligible to participate in Medicare, the OIG will provide written notice to the affected party that the State Medicaid agency will be required to suspend the party from Medicaid participation.

(b) The written notice will set forth:

(1) The basis for the suspension;

(2) The duration of the suspension and the factors considered in setting the duration;

(3) The requirements and procedure for reinstatement;

(4) The appeal rights;

(5) The fact that the State Medicaid agency is required to suspend the person from participation in the Medicaid program for the same period as he or she is suspended from Medicare participation.

§ 1001.124 Notice to others regarding suspension for conviction of program-related crime.

(a) The following groups will also be notified of the suspension concurrently with its notification to the suspended party:

(1) Any provider or supplier in which the suspended party is known to be serving as an employee, administrator, operator, or in which the party is serving in any other capacity and is receiving payment for providing services. The purpose of the notice is to inform the provider or supplier that Medicare payment will be denied for any services performed by the suspended party on or after the effective date of the suspension. However, the lack of this notice will not affect HCFA's ability to deny payment for these services;

(2) The State Medicaid agencies, in order that they can promptly suspend the party from participation in the Medicaid program (see § 1002.210 of the chapter);

(3) The State or local authority responsible for the licensing or certification of the suspended party;

(4) The public; and

(5) As appropriate—

(i) Title V agencies, States Medicaid Fraud Control Units, and PROs;

(ii) Hospitals, skilled nursing facilities, home health agencies, and health maintenance organizations (HMOs);

(iii) Medical societies and other professional organizations; and

(iv) Contractors, health care prepayment plans, and other affected agencies and organizations.

(b) The notice to the licensing or certifying authority will be accompanied by a request that the authority:

(1) Make appropriate investigations;

(2) Invoke any sanctions available under State law and the authority's policies; and

(3) Keep HCFA and the OIG fully and currently informed of any action it takes.

§ 1001.125 Duration of suspension.

(a) Suspension on the basis of a conviction of a program-related crime will continue until the suspended party is reinstated in accordance with §§ 1001.130 through 1001.136.

(b) The suspension notice will specify the earliest date on which the suspended individual may seek reinstatement. In setting that date, the OIG will consider:

(1) The number and nature of the program violations and other related offenses;

(2) The nature and extent of any adverse impact the violations have had on beneficiaries;

(3) The amount of the damages incurred by the Medicare, Medicaid, and the social services programs;

(4) Whether there are any mitigating circumstances;

(5) The length of the sentence imposed by the court;

(6) Any other facts bearing on the nature and seriousness of the program violations; and

(7) The previous sanction record of the suspended party under the Medicare or Medicaid program.

§ 1001.126 Effect of suspension.

(a) *Denial of payments to a suspended party.* (1) Payment will not be made to a suspended party (who has accepted assignment for the beneficiary's claims) for items and services furnished on or after the effective date of the suspension, except as provided in paragraph (e) of this section.

(2) An assignment of a beneficiary's claim that is made to an individual or supplier on or after the effective date of the suspension is not valid.

(b) *Denial of payments to a supplier that is wholly owned by a suspended party.* (1) Payment will not be made to a supplier (e.g., durable medical equipment supplier or laboratory) that is wholly owned by a suspended party for items or services furnished on or after the effective date of the suspension if the supplier has accepted assignment for the beneficiary's claim.

(2) An assignment of a beneficiary's claim that is made on or after the effective date of the suspension to a supplier that is wholly owned by a suspended party is not valid.

(c) *Denial of payments to a provider for services performed by a suspended party.* Payment will not be made to a provider for services performed, including services performed under contract, by a suspended party or by a supplier which is wholly owned by a suspended party, on or after the effective date of the suspension.

(d) *Denial of payment to beneficiaries.* If a beneficiary submits claims for items or services furnished by a suspended party or by a supplier which is wholly owned by a suspended party, on or after the effective date of the suspension—

(1) HCFA will pay the first claim submitted by the beneficiary and immediately give the beneficiary notice of the suspension.

(2) HCFA will not pay the beneficiary for items or services furnished more than 15 days after the date on the notice to the beneficiary.

(e) *Exceptions.* Payment is available for up to 30 days after the effective date of the suspension for—

(1) Inpatient hospital services (including inpatient psychiatric hospital services) or posthospital extended care furnished to a beneficiary who was admitted before the effective date of the suspension; and

(2) Home health services and hospice care furnished under a plan established before the effective date of the suspension.

§ 1001.128 Appeal procedures.

(a) A person suspended for conviction of a program-related crime, as specified in § 1001.122, may request a hearing before an Administrative Law Judge on the following issues:

(1) Whether he or she was, in fact, convicted;

(2) Whether the conviction was related to his or her participation in the delivery of medical care of services under the Medicare, Medicaid, or social services program; and

(3) Whether the length of the suspension is reasonable.

(b) A hearing under this section will be conducted in accordance with the procedures set forth in Subpart D of Part 498 of this title.

(c) If any party to the hearing is dissatisfied with the hearing decision, that party is entitled to request Appeals Council review of the decision as specified in Subpart E of Part 498 of this title. A suspended party may also seek judicial review of the final administrative decision.

[51 FR 34767, Sept. 30, 1986, as amended at 52 FR 22454, June 12, 1987]

REINSTATEMENT PROCEDURES

§ 1001.130 Timing and method of request for reinstatement.

(a) A practitioner, provider, or supplier of services excluded from participation for fraud and abuse under § 1001.101 and a party suspended from participation for program-related crimes under § 1001.122 may request reinstatement at any time after the date specified in the notice of exclusion or suspension by submitting to the OIG or authorizing the OIG to obtain:

(1) Statements from private health insurers, indicating whether there have been any questionable claims submitted during the period of exclusion or suspension;

(2) Statements from peer review bodies, probation officers, where appropriate, or professional associations as required by the OIG, attesting to their belief, supported by facts, the

the violations that led to exclusion or conviction will not be repeated; and

(3) A statement from the affected party setting forth the reasons why he or she should be reinstated.

§ 1001.132 Criteria for action on request for reinstatement.

(a) *OIG criteria for action.* The OIG will not approve a request for reinstatement unless it is reasonably certain that the violations that led to exclusion or conviction will not be repeated. In making this determination, the OIG will consider, among other factors:

(1) Whether the applicant has been convicted in Federal, State or local court for activities related to his or her program participation; and

(2) Whether the State or local licensing authority has taken any adverse action against the party since the date of exclusion or suspension.

(b) *Additional criteria for providers requesting reinstatement.* When the OIG approves a request from a provider requesting reinstatement, such provider may not be reinstated until the OIG determines, based on the findings of HCFA, that the provider has fulfilled or has made satisfactory arrangements to fulfill all of the statutory and regulatory responsibilities specified in its agreement.

§ 1001.134 Notice of action on request for reinstatement.

(a) *Notice of approval of request.* If the OIG approves the request for reinstatement, it will:

(1) Give written notice to the excluded or suspended party specifying the date when program participation may resume; and

(2) Given notice to the public and, as appropriate, to Title V State agencies, State Medicaid agencies and Medicaid Fraud Control Units, hospitals, skilled nursing facilities, home health agencies, medical societies, other professional societies or associations, contractors, health care prepayment plans, health maintenance organizations (HMOs), PROs, the State or local licensing or certifying authority, and other affected organizations.

(b) *Notice of denial of request.* (1) If the OIG does not approve the request for reinstatement, it will give written notice to the party.

(2) Within 30 days of the date on the notice, the excluded or suspended party may submit:

(i) Documentary evidence and written argument against the continued exclusion or suspension; or

(ii) A written request to present evidence or argument orally to an OIG official. (The decision to continue the exclusion or suspension is not an initial determination under the provisions of Part 498 of this title.)

(c) *Action following consideration of additional evidence.* After evaluating any additional evidence submitted by the excluded or suspended party (or at the end of the 30 day period, if none is submitted), the OIG will send written notice:

(1) Confirming the denial, and indicating that a subsequent request for reinstatement will not be accepted until 6 months after the date of confirmation; or

(2) Approving reinstatement and specifying the date when program participation may be resumed. If the OIG approves reinstatement, the OIG will notify the public and, as appropriate, the agencies and institutions as specified in paragraph (a)(2) of this section.

(d) The OIG must automatically reinstate a physician excluded exclusively on the basis of § 1001.102 or § 1001.104 if that exclusion has been in effect for five years.

[51 FR 34767, Sept. 30, 1986, as amended at 52 FR 11651, Apr. 10, 1987; 52 FR 22454, June 12, 1987]

§ 1001.136 Reversed or vacated convictions of program-related crime.

(a) The OIG will reinstate a suspended party whose conviction has been reversed or vacated.

(b) If a reinstatement is made under paragraph (a) of this section, HCFA will make payment, either to the party or the beneficiary, if the claim was not assigned, for services covered under Medicare that are furnished or performed during the period of suspension.

Subpart C—Termination of Agreement and Reinstatement After Termination

§ 1001.201 Termination by the OIG.

(a) *Basis for termination.* The OIG may terminate the agreement of any provider if the OIG finds that any of the following failings can be attributed to that provider:

(1) It has knowingly and willfully made, or caused to be made, any false statement or representation of a material fact for use in an application or request for payment under Medicare.

(2) It has submitted, or caused to be submitted, requests for Medicare payment of amounts that substantially exceed the costs it incurred in furnishing the services for which payment is requested.

(3) It has furnished services that the OIG has determined to be substantially in excess of the needs of individuals or of a quality that fails to meet professionally recognized standards of health care. The OIG will not terminate a provider agreement under paragraph (a) if HCFA has waived a disallowance with respect to the services in question on the grounds that the provider and the beneficiary could not reasonably be expected to know the payment would not be made. (The rules for determining such lack of knowledge are set forth in §§ 405.334 and 405.336 of this title.)

(b) *Notice of termination.* (1) The OIG will give the provider notice of termination at least 15 days before the effective date of termination of the agreement, and will concurrently give notice of termination to the public. The notice will state the reasons for, and the effective date of, the termination, and explain to what extent services may continue after that date, in accordance with the exceptions set forth in § 1001.211.

(c) *Appeal by the provider.* A provider may appeal a termination of its agreement by the OIG, in accordance with Part 498 of this title. The termination of a provider agreement by the OIG is subject to the additional procedures specified in §§ 1001.105 through 1001.109 of this chapter for notice and appeals.

[51 FR 34767, Sept. 30, 1986, as amended at 52 FR 22454, June 12, 1987]

§ 1001.211 Exceptions to effective date of termination.

Payment is available for up to 30 days after the effective date of termination for—

(a) Inpatient hospital services (including inpatient psychiatric hospital services) and posthospital extended care services furnished to a beneficiary who was admitted before the effective date of termination; and

(b) Home health services and hospice care furnished under a plan established before the effective date of termination.[1]

§ 1001.221 Reinstatement after termination.

When a provider agreement has been terminated by the OIG under § 1001.201, or by HCFA under § 489.53 of this title, a new agreement with that provider will not be accepted unless the OIG or HCFA, as appropriate, finds—

(a) That the reason for termination of the previous agreement has been removed and there is reasonable assurance that it will not recur; and

(b) That the provider has fulfilled or has made satisfactory arrangements to fulfill, all of the statutory and regulatory responsibilites of its previous agreement.

[51 FR 34767, Sept. 30, 1986; 51 FR 3757 Oct. 23, 1986]

Subpart D—Payment Denial Under the Prospective Payment System

§ 1001.301 Denial of payment as a result of admissions and quality review.

(a) A determination under § 412.48(a) of this title, related to pattern of inappropriate admissions and billing practices that have the effect of circumventing the prospective payment system, will be referre by HCFA to the OIG for a determination in accordance with sectio 1866(b)(2) of the Act. The determina tion will be effective in the manner provided in section 1866(b)(3) and (4) of the Act, and regulations in Subpart C of this Part, with respect to terminations of agreements, and will remain in effect until the OIG finds and gives reasonable notice to the public and that the basis for such determination has been removed and that there is reasonable assurance that it will not recur.

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[1] For termination before July 18, 19 payment was available through the calend year in which the termination was effecti

(b) Any party to a determination made by the OIG under paragraph (a) of this section, who is dissatisfied with that determination, is entitled to reasonable notice and opportunity for a hearing to the same extent as provided in section 205(b) of the Act and to judicial review of the final decision after hearing as provided in section 205(g) of the Act.

(c) The OIG will promptly notify each Medicaid agency of any determination made under paragraph (a) of this section.

PART 1002—PROGRAM INTEGRITY—MEDICAID

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AUTHORITY: Secs. 1102, 1124, 1126, 1128, 1902(a)(4)(A), 1902(a)(30), 1902(a)(39), 1903(a)(6), 1903(b)(3), 1903(i)(2), 1903(n), and 1903(q) of the Social Security Act; 42 U.S.C. 1302, 1320a-3, 1320a-5, 1320a-7, 1396a(a)(4)(A), 1396a(30), 1396a(39), 1396b(a)(6), 1396b(b)(3), 1396b(i)(2), 1396b(n), and 1396b(q).

SOURCE: 51 FR 34772, Sept. 30, 1986, unless otherwise noted.

Subpart A—General Provisioins

§ 1002.1 Basis and purpose.

(a) This part sets forth requirements for the prevention of fraud and abuse in the Medicaid program and implements specific statutory provisions aimed at protecting the integrity of the program.

(b) Subpart B is based on sections 1126, 1128, 1902(a)(4)(A), 1902(a)(30), 1902(a)(39) and 1903(i)(2) of the Social Security Act. It requires Medicaid agencies to—

(1) Have the ability to exclude from program reimbursement any provider that defrauds or abuses the Medicaid or Medicare program; and

(2) Suspend any individual receiving reimbursement under the Medicaid program who has been convicted of a crime related to delivery of medical care or services under the Medicare, Medicaid, or social services programs.

(c) Subpart C implements sections 1903(a)(6), 1903(b)(3), and 1903(q) of the Social Security Act, and prescribes requirements for the establishment and operation of State Medicaid fraud control units. It also details conditions that must be met in order for costs of the fraud control units to quality for 90 percent Federal financial participation (FFP).

§ 1002.2 Definitions.

As used in Suparts B and C of this part, unless the context indicates otherwise—

Abuse means provider practices that are inconsistent with sound fiscal, business, or medical practices, and result in an unnecessary cost to the Medicaid program, or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care. It also includes recipient practices that result in unnecesary cost to the Medicaid program.

Conviction or *Convicted* means that a judgment of conviction has been entered by a Federal, State, or local court, regardless of whether an appeal from that judgment is pending.

Exclusion means that items or services furnished by a specific provider who has defrauded or abused the Medicaid program will not be reimbursed under Medicaid.

Fraud means an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable Federal or State law.

Furnished refers to items and services provided directly by, or under the direct supervision of, or ordered by, a practitioner or other individual (either as an employee or in his or her own capacity), a provider, or other supplier of services. (For purposes of denial of reimbursement within this part, it does not refer to services ordered by one party but billed for and provided by or under the supervision of another.)

Practitioner means a physician or other individual licensed under State law to practice his or her profession.

PRO means Utilization and Quality Control Peer Review Organization as created by the Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. 97-248.

PSRO stands for Professional Standards Review Organization.

Suspension means that items or services furnished by a specified provider who has been convicted of a program related offense in a Federal State, or local court will not be reimbursed under Medicaid.

§ 1002.3 Disclosure by providers: Information on persons convicted of crimes.

(a) *Information that must be disclosed.* Before the Medicaid agency enters into or renews a provider agreement, or at any time upon written request by the Medicaid agency, the provider must disclose to the Medicaid agency the identity of any person who

(1) Has ownership or control interes in the provider, or is an agent or managing employee of the provider; and

(2) Has been convicted of a cirminal offense related to that person's involvement in any program under Medicare, Medicaid, or the Title XX services program since the inception of those programs.

(b) *Notification to Inspector Gene al.* (1) The Medicaid agency mus notify the Inspector General of th Department of any disclosures mad under paragraph (a) of this sectio within 20 working days from the da it receives the information.

(2) The agency must also prompt notify the Inspector General of th Department of any action it takes o the provider's application for partic pation in the program.

(c) *Denial or termination of provid participation.* (1) The Medica agency may refuse to enter into renew an agreement with a provider any person who has an ownership control interest in the provider, who is an agent or managing employ of the provider, has been convicted a criminal offense related to that person's involvement in any program established under Medicare, Medicaid or the Title XX Services Program.

(2) The Medicaid agency may refuse to enter into or may terminate a provider agreement if it determines that the provider did not fully and accurately make any disclosure required under paragraph (a) of this section.

Subpart B—Exclusion of Providers, and Suspension of Practitioners and Other Individuals

§ 1002.200 State plan requirement.

The plan must provide that the requirements of this subpart are met. However, the provisions of these regulations are minimum requirements. The agency may impose broader sanctions if it has the authority to do so under State law.

EXCLUSIONS ON BASIS OF FRAUD AND ABUSE

§ 1002.203 Exclusion of Medicaid providers for fraud and abuse.

(a) *Basis for exclusion.* The agency must have administrative procedures which enable the agency to exclude from Medicaid reimbursement a provider who it determines has:

(1) Knowingly and willfully made or caused to be made any false statement or misrepresentation of material fact in claiming, or use in determining the right to, payment under Medicaid.

(2) Furnished or ordered services under Medicaid that are substantially in excess of the recipient's needs or that fail to meet professionally recognized standards for health care; or

(3) Submitted or caused to be submitted to the Medicaid program bills or requests for payment containing charges or costs that are substantially in excess of customary charges or costs. However, the agency must not impose an exclusion under this section if it finds the excess charges are justified by unusual circumstances or medical complications requiring additional time, effort, or expense in localities in which it is accepted medical practice to make an extra charge in such case.

(b) *Reports to be considered.* The agency may base its determination that services were excessive or of unacceptable quality on reports, including sanction reports, from any of the following sources:

(1) The PRO for the area served by the provider;

(2) State or local licensing or certification authorities;

(3) Peer review committees of fiscal agents or contractors;

(4) State or local professional societies; or

(5) Other sources deemed appropriate by the Medicaid agency or the OIG.

§ 1002.204 Notice of proposed exclusion for fraud and abuse.

If the agency proposes to exclude a provider under § 1002.203 it must send the provider written notice stating the reasons for the proposed exclusion and the right to review.

§ 1002.205 Right to review.

Before imposing an exclusion, the agency must give the provider the opportunity to submit documents and written argument against the exclusion. However, the provider must be given any additional appeals rights under procedures established by the State.

§ 1002.206 Notice of exclusion for fraud and abuse.

After the review, if the agency makes a final decision to exclude—

(a) The agency must send the provider written notice 15 days before the exclusion becomes effective;

(b) The notice must state—

(1) The reasons for the decision;

(2) The effective date;

(3) The effect of the exclusion on the party's participation in the Medicaid program;

(4) The earliest date in which the agency will accept a request for reinstatement (see §§ 1002.232 and 1002.234 for reinstatement procedures); and

(5) The requirements and procedures for reinstatement.

(c) The agency must also give notice of the exclusion and the effective date to the OIG, HCFA, the public, and, as appropriate, to—

(1) Recipients;

(2) PROs;

(3) Providers and organizations;

(4) Medical societies and other professional organizations;

(5) State licensing boards and affected State and local agencies and organizations; and

(6) Medicare carriers and intermediaries.

§ 1002.207 Denial of payment and FFP: Parties excluded under Medicaid.

(a) *Denial of payment.* The agency must not make payment under Medicaid for items or services furnished by a provider who has been excluded from the Medicaid program in accordance with § 1002.203.

(b) *Denial of FFP.* FFP is not available in payments under any State plan for services furnished by a provider who has been excluded from the Medicaid program.

(c) *Duration of exclusion.* The exclusion will continue until the provider is reinstated in accordance with §§ 1002.230 through 1002.236.

(d) *When FFP will be reinstated.* FFP will be available for services furnished by a Medicaid provider after reinstatement in the Medicaid program.

§ 1002.208 Denial of FFP: Parties excluded or terminated under Medicare for fraud and abuse.

(a) *Denial of FFP.* FFP is not available in payments for services furnished by a Medicaid provider while that provider is excluded or terminated from participation, or otherwise sanctioned, because of fraud and abuse under the Medicare program under § 1001.101 of this chapter.

(b) *Effective date of denial.* Except as specified in paragraph (c) of this section, the denial of FFP will apply to services furnished on or after the effective date of the exclusion from Medicare.

(c) *Exception: FFP available in payment made during exclusion or after termination.* Payment is available for up to 30 days after the effective date of the exclusion or termination for—

(1) Inpatient hospital services (including inpatient psychiatric hospital services) and skilled nursing facility and intermediate care facility services furnished to a beneficiary who was admitted before the effective date of the exclusion or termination; and

(2) Home health services and hospital care furnished under a plan established before the effective date of the exclusion or termination.

(d) *When FFP will be reinstated.* FFP will be available for services furnished by a Medicaid provider after reinstatement in the Medicare program

SUSPENSIONS ON BASIS OF CONVICTION OF PROGRAM-RELATED CRIMES

§ 1002.210 Bases for suspension for conviction of program-related crimes.

The agency must suspend from the Medicaid program any party who has been suspended from participation in Medicare under § 1001.122 of this chapter for conviction of a program-related crime. The agency must also suspend any convicted party who is not eligible to participate in Medicare whenever the OIG directs such action.

§ 1002.211 Duration of suspension.

(a) The suspension under Medicaid must be effective on the date established by the OIG for suspension under Medicare, and must be for the same period as the Medicare suspension. In the case of a convicted party who is not eligible to participate in Medicare, the suspension will be effective on the date and for the period established by the OIG.

(b) The agency may impose a sanction under its own sanction authorities which is effective before, or extends beyond, the mandatory suspension period under paragraph (a) of this section.

§ 1002.212 Notification of State or lo convictions of crimes against Medica

(a) The agency must notify the OI whenever a State or local court has e tered a judgment of conviction agai an individual who is receiving rei bursement under Medicaid, for criminal offense related to partici tion in the delivery of medical care services under the Medicaid program

(b) If the agency was involved in t investigation or prosecution of t case, it must send notice within 15 days after the conviction.

(c) If the agency was not so involved, it must give notice within 15 days after it learns of the conviction.

(Approved by the Office of Management and Budget under control number 0938-0076)

§ 1002.213 Effect of suspension.

(a) *Denial of payment.* Except as specified in paragraph (b) of this section, the agency must not make any payment under the plan for services furnished directly by, or under the supervision of, a suspended party during the period of the suspension.

(b) *Circumstances under which payment may be made after a suspension.* Payment is available for up to 30 days after the effective date of the suspension for—

(1) Inpatient hospital services (including inpatient psychiatric hospital services) and skilled nursing facility and intermediate care facility services furnished to a beneficiary who was admitted before the effective date of the suspension; and

(2) Home health services and hospital care funished under a plan established before the effective date of the suspension.

§ 1002.214 Waiver of suspension of parties.

(a) *Request.* The agency may request the OIG to waive suspension of a party under § 1002.210 if it concludes that, because of the shortage of providers or other health care personnel in the area, individuals eligible to receive Medicaid benefits would be denied adequate access to medical care.

(b) *Notice of waiver of suspension.* The OIG will notify the agency if and when it waives suspension in response to the agency's request.

REINSTATEMENT PROCEDURES

§ 1002.230 Reinstatement of parties suspended under Medicare.

(a) The agency may not reinstate in the Medicaid program a party that has been suspended from Medicare or suspended at the direction of the OIG until the OIG notifies the agency that the party may be reinstated.

(b) If the OIG makes a determination to reinstate a party under Medicare, the agency, upon notification from the OIG, must automatically reinstate the party under Medicaid effective on the date of reinstatement under Medicare, unless a longer period of suspension was established in accordance with the State's own authorities and procedures.

§ 1002.232 Basis for reinstatement after exclusion.

(a) The provisions of this section and § 1002.234 apply to the reinstatement in the Medicaid program of all parties excluded in accordance with § 1002.203, if a State affords reinstatement opportunity to those parties.

(b) A party who has been excluded from Medicaid may be reinstated only by the Medicaid agency that imposed the exclusion.

(c) A party may submit to the agency a request for reinstatement at any time after the date specified in the notice of exclusion.

(d) In setting the earliest date on which it will consider a request for reinstatement, the agency must consider—

(1) The number and nature of the program violations and other related offenses;

(2) The nature and extent of any adverse impact the violations have had on recipients;

(3) The amount of any damages;

(4) Whether there are any mitigating circumstances; and

(5) Any other facts bearing on the nature and seriousness of the program violations or related offenses.

§ 1002.234 Action on request for reinstatement.

(a) *Criteria for approving reinstatement request.* The agency may grant reinstatement only if it is reasonably certain that the violation(s) that led to exclusion will not be repeated. In making this determination, the agency will consider, among other factors—

(1) Whether the party has been convicted in a Federal, State, or local court of other offenses related to par-

ticipation in the Medicare or Medicaid program which were not considered during the development of the exclusion; and

(2) Whether the State or local licensing authorities have taken any adverse action against the party for offenses related to participation in the Medicare or Medicaid program which were not considered during the development of the exclusion.

(b) *Notice of action on request.* (1) If the agency approves the request for reinstatement, it must give written notice to the excluded party, and to all others who were informed of the exclusion in accordance with § 1002.206, specifying the date on which Medicaid program participation may resume.

(2) If the agency does not approve the request for reinstatement, it will notify the excluded party of its decision.

Subpart C—State Medicaid Fraud Control Units

§ 1002.301 Definitions.

As used in this subpart, unless otherwise indicated by the context:

Employ or *employee*, as the context requires, means full-time duty intended to last at least a year. It includes an arrangement whereby an individual is on full-time detail or assignment to the unit from another government agency, if the detail or assignment is for a period of at least 1 year and involves supervision by the unit.

Provider means an individual or entity which furnishes items or services for which payment is claimed under Medicaid.

Unit means the State Medicaid fraud control unit.

§ 1002.303 Scope and purpose.

This subpart implements sections 1903(a)(6), 1903(b)(3), and 1903(q) of the Social Security Act, as amended by the Medicare-Medicaid Anti-fraud and Abuse Amendments (Pub. L. 95-142 of October 25, 1977). The statute authorizes the Secretary to pay a State 90 percent of the costs of establishing and operating a State Medicaid fraud control unit, as defined by the statute, for the purpose of eliminating fraud in the State Medicaid program.

§ 1002.305 Basic requirement.

A State Medicaid fraud control unit must be a single identifiable entity of the State government certified by the Secretary as meeting the requirements of §§ 1002.307 through 1002.313 of this chapter.

§ 1002.307 Organization and location requirements.

Any of the following three alternatives is acceptable:

(a) The unit is located in the office of the State attorney general or another department of State government which has statewide authority to prosecute individuals for violations of criminal laws with respect to fraud in the provision or administration of medical assistance under a State plan implementing Title XIX of the Act; or

(b) If there is no State agency with statewide authority and capability for criminal fraud prosecutions, the unit has established formal procedures which assure that the unit refers suspected cases of criminal fraud in the State Medicaid program to the appropriate State prosecuting authority or authorities, and provides assistance and coordination to such authority or authorities in the prosecution of such cases; or

(c) The unit has a formal working relationship with the office of the State attorney general and has forma procedures for referring to the attorney general suspected criminal violations occurring in the State Medica program and for effective coordinatio of the activities of both entities rela ing to the detection, investigation an prosecution of those violations. Unde this requirement, the office of th State attorney general must agree t assume responsibility for prosecutin alleged criminal violations referred t it by the unit. However, if the atto ney general finds that another pro ecuting authority has the demonstra ed capacity, experience and willin ness to prosecute an alleged violatio he or she may refer a case to th prosecuting authority, as long as t Attorney General's Office mainta oversight responsibility for the pr ecution and for coordination betwe the unit and the prosecuting authority.

§ 1002.309 Relationship to, and agreement with, the Medicaid agency.

(a) The unit must be separate and distinct from the Medicaid agency.

(b) No official of the Medicaid agency shall have authority to review the activities of the unit or to review or overrule the referral of a suspected criminal violation to an appropriate prosecuting authority.

(c) The unit shall not receive funds paid under this subpart either from or through the Medicaid agency.

(d) The unit shall enter into an agreement with the Medicaid agency under which the Medicaid agency will agree to comply with all requirements of § 455.21(a)(2) of this title.

§ 1002.311 Duties and responsibilities of the unit.

(a) The unit shall conduct a statewide program for investigating and prosecuting (or referring for prosecution) violations of all applicable State laws pertaining to fraud in the administration of the Medicaid program, the provision of medical assistance, or the activities of providers of medical assistance under the State Medicaid plan.

(b) The unit shall also review complaints alleging abuse or neglect of patients in health care facilities receiving payments under the State Medicaid plan and may review complaints of the misappropriation of patient's private funds in such facilities.

(1) If the initial review indicates substantial potential for criminal prosecution, the unit shall investigate the complaint or refer it to an appropriate criminal investigative or prosecutive authority.

(2) If the initial review does not indicate a substantial potential for criminal prosecution, the unit shall refer the complaint to an appropriate State agency.

(c) If the unit, in carrying out its duties and responsibilities under paragraphs (a) and (b) of this section, discovers that overpayments have been made to a health care facility or other provider of medical assistance under the State Medicaid plan, the unit shall either attempt to collect such overpayment or refer the matter to an appropriate State agency for collection.

(d) Where a prosecuting authority other than the unit is to assume responsibility for the prosecution of a case investigated by the unit, the unit shall insure that those responsible for the prosecutive decision and the preparation of the case for trial have the fullest possible opportunity to participate in the investigation from its inception and will provide all necessary assistance to the prosecuting authority throughout all resulting prosecutions.

(e) The unit shall make available to Federal investigators or prosecutors all information in its possession concerning fraud in the provision or administration of medical assistance under the State plan and shall cooperate with such officials in coordinating any Federal and State investigations or prosecutions involving the same suspects or allegations.

(f) The unit shall safeguard the privacy rights of all individuals and shall provide safeguards to prevent the misuse of information under the unit's control.

§ 1002.313 Staffing requirements.

(a) The unit shall employ sufficient professional, administrative, and support staff to carry out its duties and responsibilities in an effective and efficient manner. The staff must include:

(1) One or more attorneys experienced in the investigation or prosecution of civil fraud or criminal cases, who are capable of giving informed advice on applicable law and procedures and providing effective prosecution or liaison with other prosecutors;

(2) One or more experienced auditors capable of supervising the review of financial records and advising or assisting in the investigation of alleged fraud;

(3) A senior investigator with substantial experience in commercial or financial investigations who is capable of supervising and directing the investigative activities of the unit.

(b) The unit shall employ, or have available to it, professional staff who are knowledgeable about the provision of medical assistance under title XIX and about the operation of health care providers.

§ 1002.315 Applications, certification, and recertification.

(a) *Initial application.* In order to receive FFP under this subpart, the unit must submit to the Secretary, an application approved by the Governor, containing the following information and documentation.

(1) A description of the applicant's organization, structure, and location within State government, and an indication of whether it seeks certification under § 1002.307 (a), (b) or (c);

(2) A statement from the State attorney general that the applicant has authority to carry out the functions and responsibilities set forth in this subpart. If the applicant seeks certification under § 1002.307(b), the statement must also specify either that there is no State agency with the authority to exercise statewide prosecuting authority for the violations with which the unit is concerned, or that, although the State attorney general may have common law authority for statewide criminal prosecutions, he or she has not exercised that authority;

(3) A copy of whatever memorandum of agreement, regulation, or other document sets forth the formal procedures required under § 1002.307(b), or the formal working relationship and procedures required under § 1002.307(c);

(4) A copy of the agreement with the Medicaid agency required under § 1002.309;

(5) A statement of the procedures to be followed in carrying out the functions and responsibilities of this subpart;

(6) A projection of the caseload and a proposed budget for the 12-month period for which certification is sought; and

(7) Current and projected staffing, including the names, education, and experience of all senior professional staff already employed and job descriptions, with minimum qualifications, for all professional positions.

(b) *Conditions for, and notification of certification.* (1) The Secretary will approve an application only if he or she has specifically approved the applicant's formal procedures under § 1002.307 (b) or (c), if either of those provisions is applicable, and has specifically certified that the applicant meets the requirements of § 1002.307;

(2) The Secretary will promptly notify the applicant whether the application meets the requirements of this subpart and is approved. If the application is not approved, the applicant may submit an amended application at any time. Approval and certification will be for a period of 1 year.

(c) *Conditions for recertification.* In order to continue receiving payments under this subpart, a unit must submit a reapplication to the Secretary at least 60 days prior to the expiration of the 12-month certification period. A reapplication must:

(1) Advise the Secretary of any changes in the information or documentation required under paragraphs (a) (1) through (5) of this section;

(2) Provide projected caseload and proposed budget for the recertification period; and

(3) Include or incorporate by reference the annual report required under § 1002.317.

(d) *Basis for recertification.* (1) The Secretary will consider the unit's reapplication, the reports required under § 1002.317, and any other reviews or information he or she deems necessary or warranted, and will promptly notify the unit whether he or she has approved the reapplication and recertified the unit.

(2) In reviewing the reapplication the Secretary will give special attention to whether the unit has used its resources effectively in investigating cases of possible fraud, in preparing cases for prosecution, and in prosecuting cases or cooperating with the prosecuting authorities.

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§ 1002.317 Annual report.

At least 60 days prior to the expiration of the certification period, the unit shall submit to the Secretary a report covering the last 12 months (the first 9 months of the certification period for the first annual report), and containing the following information:

(a) The number of investigations initiated and the number completed or closed, categorized by type of provider;

(b) The number of cases prosecuted or referred for prosecution; the number of cases finally resolved and their outcomes; and the number of cases investigated but not prosecuted or referred for prosecution because of insufficient evidence;

(c) The number of complaints received regarding abuse and neglect of patients in health care facilities; the number of such complaints investigated by the unit; and the number referred to other identified State agencies.

(d) The number of recovery actions initiated by the unit; the number of recovery actions referred to another agency; the total amount of overpayments identified by the unit; and the total amount of overpayments actually collected by the unit;

(e) The number of recovery actions initiated by the Medicaid agency under its agreement with the unit; and the total amount of overpayments actually collected by the Medicaid agency under this agreement;

(f) Projections for the succeeding 12 months for items listed in paragraphs (a) through (e) of this section;

(g) The costs incurred by the unit;

(h) A narrative that evaluates the unit's performance; describes any specific problems it has had in connection with the procedures and agreements required under this subpart; and discusses any other matters that have impaired its effectiveness.

(Approved by the Office of Management and Budget under control number 0990-0162)

§ 1002.319 Federal financial participation (FFP).

(a) *Rate of FFP.* Subject to the limitation of this section, the Secretary will reimburse each State by an amount equal to 90 percent of the costs incurred by a certified unit which are attributable to carrying out its functions and responsibilities under this subpart.

(b) *Retroactive certification.* The Secretary may grant certification retroactive to the date on which the unit first met all the requirements of the statute and of this subpart. For any quarter with respect to which the unit is certified, the Secretary will provide reimbursement for the entire quarter.

(c) *Amount of FFP.* FFP for any quarter shall not exceed the higher of $125,000 or one-quarter of 1 percent of the sums expended by the Federal, State, and local governments during the previous quarter in carrying out the State Medicaid program.

(d) *Costs subject to FFP.* FFP is available under this subpart for the expenditures attributable to the establishment and operation of the unit, including the cost of training personnel employed by the unit. Reimbursement shall be limited to costs attributable to the specific responsibilities and functions set forth in this subpart in connection with the investigation and prosecution of suspected fraudulent activities and the review of complaints of alleged abuse or neglect of patients in health care facilities. Establishment costs are limited to clearly identifiable costs of personnel that:

(1) Devote full time to the establishment of the unit which does achieve certification; and

(2) Continue as full-time employees after the unit is certified. All establishment costs will be deemed made in the first quarter of certification.

(e) *Costs not subject to FFP.* FFP is not available under this subpart for expenditures attributable to:

(1) The investigation of cases involving program abuse or other failures to comply with applicable laws and regulations, if these cases do not involve substantial allegations or other indications of fraud;

(2) Efforts to identify situations in which a question of fraud may exist, including the screening of claims, analysis of patterns of practice, or routine verification with recipients of whether services billed by providers were actually received;

(3) The routine notification of providers that fraudulent claims may be punished under Federal or State law;

(4) The performance by a person other than a full-time employee of the unit of any management function for the unit, any audit or investigation,

any professional legal function, or any criminal, civil or administrative prosecution of suspected providers;

(5) The investigation or prosecution of cases of suspected recipient fraud not involving suspected conspiracy with a provider; or

(6) Any payment, direct or indirect, from the unit to the Medicaid agency, other than payments for the salaries of employees on detail to the unit.

§ 1002.321 Other applicable HHS regulations.

Except as otherwise provided in this subpart, the following regulations from 45 CFR Subtitle A apply to grants under this subpart:

Subpart C of Part 16—Department Grant Appeals Process—Special Provisions Applicable To Reconsideration of Disallowances (note that this applies only to disallowance determinations and not to any other determinations, e.g., over certification or recertification)
Part 74—Administration of Grants
Part 75—Informal Grant Appeals Procedures
Part 80—Nondiscrimination Under Programs Receiving Federal Assistance Through the Department of Health and Human Services; Effectuation of Title VI of the Civil Rights Act of 1964
Part 81—Practice and Procedure for Hearings Under 45 CFR Part 80
Part 84—Nondiscrimination on the Basis of Handicap in Programs and Activities Receiving or Benefiting From Federal Financial Assistance

PART 1003—CIVIL MONEY PENALTIES AND ASSESSMENTS

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AUTHORITY: Secs. 1102, 1128, 1128A, 1842(j) and 1842(k) of the Social Security Act (42 U.S.C. 1302, 1320a-7, 1320a-7a, 1395u(j) and 1395u(k)).

SOURCE: 51 FR 34777, Sept. 30, 1986, unless otherwise noted.

§ 1003.100 Basis and purpose.

(a) *Basis.* This part implements sections 1128(c), 1128A, 1842(j), and 1842(k) of the Social Security Act (42 U.S.C. 1320a-7(c), 1320a-7a, 1395u(j), and 1395u(k)).

(b) *Purpose.* This part (1) establishes procedures for imposing civil money penalties and assessments against persons who have submitted certain prohibited claims under the Medicare, Medicaid, or the Maternal and Child Health Services Block Grant programs; (2) establishes procedures for suspending from the Medicare and Medicaid programs, persons against whom a civil money penalty or assessment has been imposed; and (3) specifies the appeal rights of persons subject to a penalty or assessment.

[51 FR 34777, Sept. 30, 1986, as amended 52 FR 11652, Apr. 10, 1987]

§ 1003.101 Definitions.

For purposes of this part:

Act means the Social Security Act.

Agent includes a Medicare fiscal intermediary or carrier, a Medicaid fiscal agent, or any other claims processing agent under the Medicare, Medicaid, or Maternal and Child Health Services Block Grant program.

ALJ means an Administrative Law Judge.

Assessment means the amount described in § 1003.104, and includes the plural of that term.

Claim means an application submitted by a person to an agency of the United States or of a State, or an agent thereof, for payment for:

(a) An item or service for which payment may be made under Medicare, or

(b) An item or service for which medical assistance is provided under a State plan for medical assistance, or

(c) An item or service for which payment may be made under the Maternal and Child Health Services Block Grant program.

Department means the Department of Health and Human Services.

General Counsel means the General Counsel of the Department or his or her designees.

HCFA means the Health Care Financing Administration.

Inspector General means the Inspector General of the Department or his or her designees.

Item or *service* includes (a) any item, device, medical supply or service claimed to have been provided to a patient and listed in an itemized claim for program payment or a request for payment, and (b) in the case of a claim based on costs, any entry or omission in a cost report, books of account or other documents supporting the claim.

Maternal and Child Health Services Block Grant program means the program authorized under Title V of the Act.

Medicaid means the program of grants to the States for medical assistance authorized under title XIX of the Act.

Medicare means the program of health insurance for the aged and disabled authorized under Title XVIII of the Act.

Penalty means the amount described in § 1003.103 and includes the plural of that term.

Person means an individual, trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private.

Program means the Medicare, Medicaid or Maternal and Child Health Services Block Grant program.

Request for payment means an application submitted by a person to any person for payment for an item or service covered under the Medicare, Medicaid or Maternal and Child Health Services Block Grant program.

Respondent means the person upon whom the Secretary has imposed, or proposes to impose, a penalty or assessment.

Secretary means the Secretary of the Department or his or her designees.

State includes the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands.

Suspension means the temporary barring or permanent exclusion of a person from participation in the Medicare or Medicaid programs under section 1128(b) of the Social Security Act.

§ 1003.102 Basis for civil money penalties and assessments.

(a) The OIG may impose a penalty and assessment against any person whom it determines in accordance with this part has presented or caused to be presented a claim which is for an item or service:

(1) That the person knew or had reason to know was not provided as claimed; or

(2) For which no payment could be made under the program under which it was submitted because:

(i) The person had been excluded under section 1128 of the Act (42 U.S.C. 1320a-7);

(ii) The person had been excluded from eligibility to provide services on a reimbursement basis under section 1160(b) of the Act as that section read prior to enactment of Pub. L. 97-248 (42 U.S.C. 1320c-9(b));

(iii) Payment had been prohibited under Title XVIII of the Act because of a determination under section

1862(d) of the Act (42 U.S.C. 1395y(d)); or

(iv) The Secretary had initiated termination proceedings against the person pursuant to a determination by the Secretary under section 1866(b)(2) of the Act (42 U.S.C. 1395cc(b)(2)).

(b) The OIG may impose a penalty against any person whom it determines in accordance with this part:

(1) Has presented or caused to be presented a request for payment in violation of the terms of:

(i) An agreement to accept payments on the basis of an assignment under section 1842(b)(3)(B)(ii) of the Act;

(ii) An agreement with a State agency not to charge a person for an item or service in excess of the amount permitted to be charged; or

(iii) An agreement to be a participating physician or supplier under section 1842(h)(1); or

(2) Is a non-participating physician under section 1842(j) of the Act and has knowingly and willfully billed individuals enrolled under Part B of Title XVIII of the Act, during the statutory period of the freeze, for actual charges in excess of such physicians, actual charges for the calendar quarter beginning on April 1, 1984.

(3) Is a physician who has knowingly and willfully—

(i) Billed for services as an assistant at surgery during a routine cataract operation, or

(ii) Included in his or her bill the services of an assistant at surgery during a routine cataract operation; and has not received prior approval from the appropriate Peer Review Organization or Medicare carrier for such services based on the existence of a complicating medical condition.

(c)(1) In any case in which it is determined that more than one person was responsible for presenting or causing to be presented a claim as described in paragraph (a) of this section, each such person may be held liable for the penalty prescribed by this part, and an assessment may be imposed against any one such person or jointly and severally against two or more such persons, but the aggregate amount of the assessments collected may not exceed the amount that could be assessed if only one person was responsible.

(2) In any case in which it is determined that more than one person was responsible for presenting or causing to be presented a request for payment described in paragraph (b) of this section, each such person may be held liable for the penalty prescribed by this part.

[51 FR 34777, Sept. 30, 1986, as amended at 52 FR 11652, Apr. 10, 1987]

§ 1003.103 Amount of penalty.

The OIG may impose a penalty of not more than $2,000 for each item or service that is subject to a determination under § 1003.102.

§ 1003.104 Amount of assessment.

A person subject to a penalty determined under § 1003.102(a) may be subject, in addition, to an assessment of not more than twice the amount claimed for each item or service which was a basis for the penalty. The assessment is in lieu of damages sustained by the Department or a State agency because of that claim.

§ 1003.105 Suspension from participation in Medicare or Medicaid.

(a) A person subject to a penalty or assessment determined under § 1003.102 may, in addition, be suspended from participation in Medicare for a period of time determined under § 1003.107. The OIG may require the appropriate State agency to suspend the person from the Medicare program for a period he shall specify. The State agency may request the Secretary to waive suspension of a person from the Medicaid program under this section if it concludes that, because of the shortage of providers or other health care personnel in the area, individuals eligible to receive Medicaid benefits would be denied access to medical care or that such individuals would suffer hardship. The Secretary will notify the State agency if and when the Secretary waives suspension in response to such a request.

(b) Any suspension under this section shall become effective only after there is a final decision of the Secretary pursuant to § 1003.125(f), or any earlier date that the respondent fails, within the time permitted, to exercise his or her right to a hearing under § 1003.109 or administrative review under § 1003.125. The effect of such suspension shall be governed by 42 CFR § 1001.126.

(c) When the Inspector General proposes to suspend a long-term care facility from the Medicare and Medicaid programs, he or she shall, at the same time he or she notifies the respondent, notify the appropriate State Office of Aging, the long-term care ombudsman, and the State Medicaid agency of the Inspector General's intention to suspend the facility.

§ 1003.106 Determinations regarding the amount of the penalty and assessment.

(a) In determining the amount of any penalty or assessment, the Department shall take into account, in accordance with this section:

(1) The nature of the claim or request for payment and the circumstances under which it was presented,

(2) The degree of culpability of the person submitting the claim or request for payment,

(3) The history of prior offenses of the person submitting the claim or —equest for payment,

(4) The financial condition of the person presenting the claim or request for payment, and

(5) Such other matters as justice may require.

(b) *Guidelines for determining the amount of the penalty or assessment.* As guidelines for taking into account the factors listed in paragraph (a), of this section, the following circumstances are to be considered:

(1) *Nature and circumstances of the claim.* It should be considered a mitigating circumstance if all the items or services subject to a determination under § 1003.102 included in the action brought under this part were of the same type and occurred within a short period of time, there were few such items or services, and the total amount claimed for such items or services was less than $1,000. It should be considered an aggravating circumstance if such items or services were of several types, occurred over a lengthy period of time, there were many such items or services (or the nature and circumstances indicate a pattern of claims for such items or services), or the amount claimed for such items or services was substantial.

(2) *Degree of culpability.* It should be considered a mitigating circumstance if the claim for the item or service was the result of an unintentional and unrecognized error in the process respondent followed in presenting claims, and corrective steps were taken promptly after the error was discovered. It should be considered an aggravating circumstance if the respondent knew the item or service was not provided as claimed, or if the respondent knew that no payment could be made because he had been excluded from program reimbursement as specified in § 1003.102(a)(2) or because payment would violate the terms of an assignment agreement or an agreement with a State agency under § 1003.102(b).

(3) *Prior offenses.* It should be considered an aggravating circumstance if at any time prior to the presentation of any claim which included an item or service subject to a determination under § 1003.102, the respondent was held liable for criminal, civil, or administrative sanctions in connection with a program covered by this part or any other public or private program of reimbursement for medical services.

(4) *Financial condition.* It should be considered a mitigating circumstance if imposition of the penalty or assessment without reduction will jeopardize the ability of the respondent to continue as a health care provider. In all cases, the resources available to the respondent will be considered when determining the amount of the penalty and assessment.

(5) *Other matters as justice may require.* Other circumstances of an aggravating or mitigating nature should be taken into account if, in the interests of justice, they require either a reduction of the penalty or assessment or an increase in order to assure the achievement of the purposes of this part.

(c) As guidelines for determining the amount of the penalty and assessment to be imposed, for every item or service subject to a determination under § 1003.102:

(1) If there are substantial or several mitigating circumstances, the aggregate amount of the penalty and assessment should be set at an amount sufficiently below the maximum permitted by §§ 1003.103 and 1003.104, to reflect that fact.

(2) If there are substantial or several aggravating circumstances, the aggregate amount of the penalty and assessment should be set at an amount sufficiently close to or at the maximum permitted by §§ 1003.103 and 1003.104, to reflect that fact.

(3) Unless there are extraordinary mitigating circumstances, the aggregate amount of the penalty and assessment should never be less than double the approximate amount of damages sustained by the United States, or any State, as a result of claims subject to a determination under § 1003.102.

(d) The guidelines set forth in this section are not binding. Moreover, nothing in this section shall limit the authority of the Department to settle any issue or case as provided by § 1003.126, or to compromise any penalty and assessment as provided by § 1003.128.

[51 FR 34777, Sept. 30, 1986; 51 FR 39528, Oct. 29, 1986]

§ 1003.107 Determinations regarding suspension.

In determining whether to suspend a person and the duration of a suspension, the Department will take into account the circumstances set forth in § 1003.106(a) and described in § 1003.106(b). Where there are aggravating circumstances as described in § 1003.106(b), the person should be suspended. The guidelines set forth in this section are not binding. Moreover, nothing in this section shall limit the authority of the Department to settle any issue or case as provided by § 1003.126 or to compromise any suspension as provided by § 1003.128.

§ 1003.108 Penalty not exclusive.

A penalty imposed under this part is in addition to any other penalties prescribed by law.

§ 1003.109 Notice of proposed determination.

(a) If the Inspector General proposes to impose a penalty and assessment, or to suspend a respondent from participation in Medicare or Medicaid in accordance with this part, he or she must deliver or send by certified mail, return receipt requested, to the respondent, written notice of his or her intent to impose a penalty, assessment and suspension, as applicable. The notice will include reference to the statutory basis for the penalty, assessment, and suspension; description of the claims and requests for payment with respect to which the penalty, assessment, and suspension are proposed (except in cases where the Inspector General is relying upon statistical sampling pursuant to § 1003.113, in which case the notice shall describe those claims and requests for payment comprising the sample upon which the Inspector General is relying and shall also briefly describe the statistical sampling technique utilized by the Inspector General); the reason why such claims and requests for payment subject the respondent to a penalty, assessment, and suspension; the amount of the proposed penalty, assessment and the period of proposed suspension (where applicable); any circumstances described in § 1003.106 which were considered when determining the amount of the proposed penalty and assessment and the period of suspension; instructions for responding to the notice, including a specific statement of respondent's right to a hearing, of the fact that failure to request a hearing within 30 days permits the imposition of the proposed penalty, assessment, and suspension without right to appeal, and of respondent's right to request an extension of time in which to respond to the notice and a copy of the rules contained in this part.

(b) Within 30 days of the date of receipt of the notice, the respondent may submit:

(1) A written statement accepting imposition of the penalty, assessment and suspension as proposed; or

(2) A written request for a hearing which shall be accompanied by an answer to the notice that

(i) With respect to the claims and requests for payment identified in the notice, admits or denies that the respondent presented or caused to be presented such claims and requests for payment,

(ii) States any defense on which the respondent intends to rely, and

(iii) May state any reasons which respondent contends should result in a reduction or modification of a penalty, assessment, and suspension.

(c) The Inspector General may extend the 30 day period for good cause shown by the respondent upon request made prior to the expiration of the 30 day period.

§ 1003.110 Failure to request a hearing.

If the respondent does not request a hearing within the time prescribed by § 1003.109 (b) and (c), the Inspector General may impose the proposed penalty, assessment, and suspension, or any less severe penalty, assessment, and suspension. The Inspector General shall notify the respondent by certified mail, return receipt requested, of any penalty, assessment, and suspension that has been imposed and of the means by which the respondent may satisfy the judgment. The respondent has no right to appeal a penalty, assessment, and suspension, with respect to which he or she has not requested a hearing.

§ 1003.111 Initiation of hearing.

If the respondent requests a hearing in accordance with § 1003.109(b)(2), determination of the penalty, assessment, and suspension will be assigned to an ALJ for hearing.

§ 1003.112 Parties.

The Inspector General and the respondent are parties to the hearing.

§ 1003.113 Notice of hearing.

The ALJ will send written notice to the respondent and to the Inspector General stating the time and place for the hearing and the issues that will be considered. In fixing the time and place of the hearing, the ALJ will attempt to minimize the costs to the parties.

§ 1003.114 Issues and burden of proof.

(a) To the extent that a proposed penalty and assessment is based on claims or requests for payment presented on or after August 13, 1981, the Inspector General must prove by a preponderance of the evidence that the respondent presented or caused to be presented such claims or requests for payment as described in § 1003.102.

(b) To the extent that a proposed penalty and assessment is based on claims presented before August 13, 1981, the Inspector General must prove by clear and convincing evidence that:

(1) The respondent presented or caused to be presented such claims as described in § 1003.102; and

(2) Presenting or causing to be presented such claims could have rendered respondent liable under the provisions of the False Claims Act, 31 U.S.C. 3729 *et seq.*, for payment of an amount not less than that proposed.

(c) Where a final determination that the respondent presented or caused to be presented a claim or request for payment falling within the scope of § 1003.102 has been rendered in any proceeding in which the respondent was a party and had an opportunity to be heard, the respondent shall be bound by such determination in any proceeding under this part.

(d) The respondent shall bear the burden of producing and proving by a preponderance of the evidence any circumstances described in § 1003.106 that would justify reducing the amount of the penalty or assessment, or the period of suspension.

§ 1003.115 Authority of ALJ.

(a) The ALJ will conduct a fair hearing, avoid delay, maintain order, and assure that a record of the proceeding is made.

(b) The ALJ shall have the authority to:

(1) Change the date, time, and place of the hearing, upon notice to the parties;

(2) Continue or recess the hearing in whole or in part for a reasonable period of time;

(3) Hold conferences to identify or simplify the issues, or to consider other matters that may aid in the expeditious disposition of the proceeding;

(4) Administer oaths and affirmations;

(5) Issue subpoenas in hearings involving Medicare and Medicaid claims;

(6) Rule on motions and other procedural matters;

(7) Regulate the course of the hearing and the conduct of counsel;

(8) Examine witnesses;

(9) Receive, rule on, exclude, or limit evidence;

(10) Upon motion of a party, decide cases, in whole or in part, by summary judgment where there is no disputed issue of material fact;

(11) Issue a written opinion containing findings of fact, conclusions of law, and an initial decision on whether a penalty or assessment or suspension should be imposed, and if so, the amount.

(c) The ALJ does not have the authority to decide upon the validity of Federal statutes or regulations.

(d)(1) The ALJ shall schedule a prehearing conference at a reasonable time in advance of the hearing, at which the parties or their counsel shall meet with the ALJ to consider:

(i) Simplification of the issues;

(ii) The necessity or desirability of amendments to pleadings for purposes of clarification, simplification, or limitation;

(iii) Stipulations, admissions of fact or the contents and authenticity of documents;

(iv) Limitation of the number of witnesses;

(v) Scheduling dates for the exchange of witness lists and of proposed exhibits; and

(vi) Such other matters as may tend to expedite the disposition of the proceedings.

(2) The ALJ shall issue an order containing all matters described in paragraph (d)(1) of this section agreed upon by the parties or ordered by the ALJ.

[51 FR 34777, Sept. 30, 1986; 51 FR 39528, Oct. 29, 1986]

§ 1003.116 Rights of parties.

(a) All parties may:

(1) Appear by counsel (or, in the case of a government agency, other authorized representative) in all a hearing proceedings.

(2) Participate in any prehearing or posthearing conference held by the ALJ.

(3) Agree to stipulations as to facts which will be made part of the record.

(4) Make opening statements at the hearing.

(5) Present material evidence which is relevant to the issues at the hearing.

(6) Present witnesses who then must be available for cross-examination by all other parties

(7) Present oral arguments at the hearing.

(8) Submit written briefs, proposed findings of fact, and proposed conclusions of law, after the hearing.

(b)(1) A party wishing to procure the appearance and testimony at the hearing of any person having personal knowledge of the matters in issue may serve on the person a notice to appear as witness. The notice shall set forth the time, date, and place at which the person is to appear for the purpose of giving testimony and the categories of documents the witness is to bring to the hearing, if any. A copy of the notice shall be filed with the ALJ and additional copies shall be served upon all parties.

(2)(i) In all hearings, it shall be the obligation of each party to produce for examination any person, along with such documents as may be requested at the time and place, and on the date set forth in a notice to appear as witness, if that party has control over such person.

(ii) In hearings involving Medicare and Medicaid claims, a notice to appear as witness may be accompanied by an administrative subpoena. A party who desires the issuance of a subpoena shall, not less than 15 days prior to the time fixed for a hearing file with the ALJ a written request therefor, designating the witness(es) or document(s) to be produced and describing the address and location thereof with sufficient particularity to permit such witness(es) or document(s) to be found. A subpoena issued under this section shall be in the name of the Secretary. The party requesting the subpoena shall pay the cost of service and the fees and the mileage of any witnesses so subpoenaed, as provided in 28 U.S.C. 1821. Subpoenas shall be served by the party requesting issuance in the manner provided in section 205(d) of the Act. A check for witness fees and mileage shall accompany the subpoena when served.

(3) A party or prospective witness may file an objection to notice to appear as witness or, in the case of a subpoena a motion to quash within five days after the notice or subpoena is served, stating with particularity the reasons why the party should not be required to produce a requested witness or why the prospective witness should not be required to appear. Where the party serving the notice has reason to believe that the party being served is likely to refuse to produce the requested witness, that party may move for an order enforcing the notice to appear as witness. Upon the failure of any person to comply with a subpoena issued under this section, the Secretary shall institute enforcement proceedings before the appropriate district court pursuant to section 205(e) of the Act, unless in the judgment of the Secretary the enforcement of such subpoena would be inconsistent with law or the purposes of the Act.

[51 FR 34777, Sept. 30, 1986; 51 FR 37577, Oct. 23, 1986; 51 FR 39528, Oct. 29, 1986]

§ 1003.117 Discovery.

(a) Upon request of a party, the ALJ shall allow that party to inspect and copy all documents, unless privileged, relevant to the issues in the proceeding that are in the possession or control of the other party. Depositions, interrogatories, and other forms of discovery are not authorized except as provided for in paragraph (b) of this section. Nothing in this section shall be construed as requiring the disclosure of internal government documents prepared in conjunction with the investigation or litigation of the case.

(b) In those cases in which the Inspector General intends to introduce the results of a statistical sampling study as evidence at the hearing pursuant to § 1003.133, the Inspector General, upon request of the respondent, shall make available for deposition, the individual(s) responsible for conducting the statistical sampling study. Should respondent intend to introduce expert testimony to rebut the statistical sampling study at the hearing, the respondent shall, upon request of the Inspector General, make available for deposition the expert witness or witnesses who will be called to so testify at the hearing. Such depositions shall be conducted in accordance with Rules 28 and 30 of the Federal Rules of Civil Procedure. Such depositions may be used by an adverse party for any purpose at the hearing. The failure of a party to make witnesses available for deposition pursuant to this section shall serve to bar the introduction of testimony or other evidence from those witnesses at the hearing.

(c)(1) Witness lists, prior statements of witnesses, and hearing exhibits shall be exchanged at least 15 days in advance of the hearing, or such other later time as is set by the ALJ. Each party shall provide to the other party copies of all exhibits that it then plans to use at the hearing.

(2) All discovery shall be concluded at least 30 days prior to the hearing or by such other later time as ordered by the ALJ. The ALJ shall, however, allow adequate time for discovery.

§ 1003.118 Evidence and witnesses.

(a) Testimony at the hearing is given orally and under oath or affirmation. Written direct testimony may be used in the discretion of the ALJ. Witnesses must be available at the hearing for cross-examination by all parties.

(b) The parties may agree to stipulations of fact. Such stipulations, or any exhibit proposed by a party, must be exchanged at a prehearing conference or otherwise prior to the hearing, if the ALJ so decides.

(c) Technical rules of evidence are not applicable to the hearing, except

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that when reasonably necessary, the ALJ must apply rules or principles designed to assure production of the most credible evidence available and to subject testimony to test by cross-examination.

(d) A witness may be cross-examined on any matter relevant to the proceeding without regard to the scope of his or her direct examination.

(e) The ALJ shall exclude irrelevant, immaterial, or unduly repetitious evidence.

(f) All documents and other evidence offered or taken for the record shall be open to examination by the parties.

§ 1003.119 Exclusion from the hearing for misconduct.

Disrespectful or disorderly language or conduct, refusal to comply with directions, or continued use of dilatory tactics by any individual at the hearing constitutes grounds for immediate exclusion of that individual from the hearing by the ALJ.

§ 1003.120 Ex parte contacts.

(a) Except for matters related to the issuance of ex parte subpoenas, the ALJ may not consult or be consulted by a party or any other individual (except employees of his or her own office) on any matter in issue, unless on notice and opportunity for all parties to participate.

(b) The ALJ shall not consider letters or other contacts from non-parties expressing views or urging action.

§ 1003.121 Separation of functions.

An employee or an agent of the Department, who is engaged in the performance of investigative or prosecutive functions for or on behalf of the Department in a case may not, in that or a factually related case, participate or advise in the decision, except as witness or counsel in public proceedings.

§ 1003.122 Official transcript.

The hearing will be recorded and transcribed. Transcripts may be obtained from the reporter by a party or the public at not to exceed the maximum rates fixed by contract between the Department and the reporter.

§ 1003.123 Post-hearing briefs.

The ALJ shall fix the time for filing post-hearing briefs, which shall not exceed 30 days from the date of receipt of the hearing transcript by the parties. Upon motion by a party, the ALJ may extend the time in which to file post-hearing briefs for a period of up to 60 days where the hearing was of unusual length or complexity or for other good cause shown. Such briefs may contain proposed findings of fact and conclusions of law. The ALJ may permit the parties to file reply briefs.

§ 1003.124 Record for decision.

The transcript of testimony, exhibits, and all papers, requests and rulings filed or made in the proceedings, constitute the exclusive record for the ALJ's initial decision.

§ 1003.125 Initial decision; administrative review; finality.

(a) The ALJ shall serve the initial decision on all parties within 60 days after the time for submission of post-hearing briefs and reply briefs (if permitted) has expired.

(b) The initial decision shall contain findings of fact, conclusions of law, and the amount of any penalties and assessments (which may be the amount proposed by the Inspector General, or a greater or lesser amount), and the length of any suspension (which may be for the period proposed by the Inspector General, or a greater or lesser peirod of time), imposed upon the respondent thereby.

(c) The findings of fact shall include a finding on each of the following issues for every item or service with respect to which a penalty or assessment was proposed.

(1) Whether the item or service is subject to a determination under § 1003.102;

(2) If the item or service is subject to a determination under § 1003.102 whether there are mitigating or aggravating circumstances as described in § 1003.106(b).

(d) The initial decision of the ALJ becomes final and binding on the parties 30 days after notice thereof is received by the respondent, unless on or before that 30th day a party files with the ALJ written exception to the initial decision and supporting reasons for the exceptions.

(e) A party opposing exceptions may file a brief in opposition to exceptions within 30 days after receipt of the exceptions or may file a brief which is limited to the issue of whether or not the Secretary should review the initial decision of the ALJ.

(f)(1) If a party timely files exceptions under paragraph (d) of this section, the ALJ will forward to the Secretary the record of the proceeding, the exceptions and reasons therefor, and any briefs filed in opposition.

(2) After the Secretary receives the initial decision, the record on which it is based, and submissions of the parties made subsequent to the decision, the Secretary will determine whether he or she will review the initial decision of the ALJ.

(3) In any case in which the Secretary decides to review the initial decision of the ALJ, he or she will inform each party of this decision by written notice. A party opposing exceptions may file a brief addressing any relevant issues not addressed in any brief filed under paragraph (e) of this section within 30 days after receipt of the Secretary's written notice under this paragraph. After the Secretary has reviewed the initial decision, the record on which it is based, and submissions of the parties made subsequent to the decision, the Secretary will affirm, modify, or reverse the initial decision, or remand the case to an ALJ. The Secretary may modify the penalty, assessment, or suspension, to be more or less severe than that imposed by the ALJ. There is no right to appear personally before the Secretary. A copy of the decision of the Secretary will be sent to the respondent by certified mail, mailed return receipt requested, and served upon the Inspector General. Except in the case of a remand, the decision of the Secretary becomes final and binding on the parties 60 days after notice thereof is received by the respondent.

(4) In any case in which the Secretary declines to review the initial decision of the ALJ, he or she will notify the respondent by certified mail, return receipt requested, and inform the Inspector General of this decision. The initial decision of the ALJ becomes final and binding on the parties 60 days after the Secretary's notice is received by the respondent.

(5)(i) The respondent may file with the ALJ a request for stay of the effective date of the final decision pending appeal. Such request shall state the grounds upon which respondent relies in requesting the stay, together with a copy of the notice(s) of appeal filed by respondent seeking review of the decision of the Secretary. The filing of such a request shall automatically act to stay the effective date of the decision of the Secretary until such time as the ALJ rules upon the request.

(ii) The Inspector General may file an opposition to respondent's request for a stay within 10 days of receipt of the request. If the Inspector General fails to file such an opposition within the allotted time, or indicates that he or she has no objection to the request, the ALJ shall grant the stay without requiring respondent to give a bond or other security.

(iii) In those cases in which the Inspector General opposes respondent's request for a stay, the ALJ may grant respondent's request where justice so requires and to the extent necessary to prevent irreparable harm. An ALJ may grant an opposed request to stay a final decision requiring the payment of money only upon the respondent's giving of a bond or other adequate security. The ALJ shall rule upon an opposed request for stay within 10 days of the receipt of the opposition of the Inspector General. A decision of the ALJ denying respondent's request for a stay shall constitute final agency action.

§ 1003.126 Settlement.

The Inspector General has exclusive authority to settle any issues or case, without the consent of the ALJ or the Secretary, at any time prior to a final decision by the Secretary. Thereafter, the General Counsel has such exclusive authority.

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§ 1003.127 Judicial review.

(a) Section 1128A(d) of the Act authorizes judicial review of a penalty or assessment imposed under § 1003.110 or § 1003.125 that has become final. Judicial review may be sought by a respondent only with respect to a penalty or assessment with respect to which the respondent filed an exception under § 1003.125(d) unless the failure or neglect to urge such exception shall be excused by the court pursuant to section 1128A(d) because of extraordinary circumstances.

(b) Section 1128(d) of the Act authorizes judicial review of a determination to bar a person from participation in Medicare or Medicaid pursuant to section 1128(b) of the Act. Judicial review may be sought by a respondent only with respect to a suspension with respect to which the respondent filed an exception under § 1003.125(d) unless the failure or neglect to urge such exception shall be excused because of extraordinary circumstances.

§ 1003.128 Collection of penalty and assessment.

(a) Once a determination by the Secretary has become final under § 1003.125(f), collection of any penalty and assessment shall be the responsibility of HCFA, except in the case of the Maternal and Child Health Services Block Grant, where the collection shall be the responsibility of the Public Health Service.

(b) A penalty and assessment imposed under this part may be compromised by the General Counsel, after consultation with the Inspector General, and may be recovered in a civil action brought in the United States district court for the district where the claim was presented, or where the respondent resides.

(c) The amount of a penalty and assessment when finally determined, or the amount agreed upon in compromise, may be deducted from any sum then or later owing by the United States, or by a State agency, to the respondent.

(d) Matters that were raised or that could have been raised in a hearing before an ALJ or in an appeal under section 1128A(d) of the Act may not be raised as a defense in a civil action by the United States to collect a penalty under this part.

§ 1003.129 Notice to other agencies.

Whenever a penalty and assessment or suspension imposed under this part becomes final, the following organizations and entities will be notified—the appropriate State or local medical or professional association, the appropriate Peer Review Organization, the State Medicaid agency, the appropriate Medicare carrier or intermediary, the appropriate State or local licensing agency or organization (including the Medicare and Medicaid State survey agencies), the long-term care ombudsman, and where appropriate, the State agency administering a Maternal and Child Health Services Block Grant Program, that the penalty and assessment or suspension have become final and the reasons for them. In cases involving suspensions, notice will also be given to the public of the suspension and its effective date. HCFA will also provide to the State Medicaid agency will also receive the notice required under section 1128(b) of the Social Security Act.

§ 1003.130 Form, filing and service of papers; computation of time; motions, disposition of motions.

(a) *Form, filing and service of papers*—(1) *Form.* The original and one copy of all papers in a proceeding conducted under this part shall be filed with the ALJ assigned to the case or with the Chief ALJ if the case has not been assigned. Every pleading and paper filed in the proceeding shall contain a caption setting forth the title of the action, the case file number assigned by the ALJ, and a designation of the paper (e.g., motion for summary judgment). The paper shall be signed and shall contain the address and telephone number of the person representing the party or the person on whose behalf the paper was filed. Unless the ALJ otherwise orders with respect to specific papers in a specific case, all such papers are public documents. Papers are considered filed when they are received by the ALJ.

(2) *Service.* Service upon any party shall be made by the party filing the

document by delivering or mailing a copy to the party's last known address. When a party is represented by an attorney, service shall be made upon the attorney.

(3) *Proof of service.* A certificate of the person serving the document by personal delivery or by mailing, setting forth the manner of service, shall be proof of service.

(b) *Computation of time.* In computing any period of time under these rules or in an order issued hereunder, the time begins with the day following the act, event, or default, and includes the last day of the period, unless it is a Saturday, Sunday, or legal holiday observed by the Federal government, in which event it includes the next business day. When the period of time allowed is less than seven days, intermediate Saturdays, Sundays, and legal holidays observed by the Federal government shall be excluded from the computation.

(c) *Motions, disposition of motions*—(1) *Motions.* Motions shall state the relief sought, the authority relied upon and the facts alleged, and shall be filed with the ALJ. If made before or after the hearing itself, the motions shall be in writing. If made at the hearing, motions may be stated orally; but the ALJ may require that they be reduced to writing and filed and served on all parties in the same manner as a formal motion. Unless otherwise ordered by the ALJ, written motions shall be accompanied by a supporting memorandum. Within 10 days after a written motion is served, or such other time period as may be fixed by ALJ, any party may file a response to a motion.

(2) *Disposition of motions.* The ALJ may not grant a written motion prior to expiration of the time for filing responses thereto, except upon consent of the parties or following a hearing, but may overrule or deny such motion without awaiting response. The ALJ shall make every reasonable effort to dispose of all outstanding motions prior to the beginning of the hearing.

§ 1003.131 Records to be public.

All documents contained in the records of formal proceedings for imposing a penalty and assessment or suspension under this part may be inspected and copied, unless ordered sealed by the ALJ.

§ 1003.132 Limitations.

No action under this part shall be entertained unless commenced, pursuant to § 1003.109(a) of this part, within six years from the date on which the claim was presented.

[52 FR 49413, Dec. 31, 1987]

§ 1003.133 Statistical sampling.

(a) In meeting the burden of proof set forth in § 1003.114, the Inspector General may introduce the results of a statistical sampling study as evidence of the number and amount of claims and/or requests for payment as described in § 1003.102 that were presented or caused to be presented by respondent. Such a statistical sampling study, if based upon an appropriate sampling and computed by valid statistical methods, shall constitute prima facie evidence of the number and amount of claims or requests for payment as described in § 1003.102.

(b) Once the Inspector General has made a prima facie case as described in paragraph (a) of this section, the burden of production shall shift to respondent to produce evidence reasonably calculated to rebut the findings of the statistical sampling study. The Inspector General will then be given the opportunity to rebut this evidence.

PART 1004—IMPOSITION OF SANCTIONS ON HEALTH CARE PRACTITIONERS AND PROVIDERS OF HEALTH CARE SERVICES BY A PEER REVIEW ORGANIZATION

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Subpart E—Effect and Duration of Exclusion

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1004.120 Reinstatement after exclusion.

Subpart F—Appeals

1004.130 Appeal rights.

AUTHORITY: Secs. 1102 and 1156 of the Social Security Act (42 U.S.C. 1302 and 1320c-5).

SOURCE: 51 FR 34783, Sept. 30, 1986, unless otherwise noted.

Subpart A—General Provisions

§ 1004.1 Scope and definitions.

(a) *Scope.* This part implements section 1156 of the Act (PROs) by—

(1) Setting forth certain obligations imposed on practitioners and providers of services under Medicare;

(2) Establishing criteria and procedures for the reports required from PSROs and PROs when there is failure to meet those obligations;

(3) Specifying the policies and procedures for making determinations on violations and imposing sanctions; and

(4) Defining the procedures for appeals by the affected party and the procedures for reinstatements.

(b) *Definitions.* As used in this part, unless the context indicates otherwise:

Economically means that services are provided at the least expensive, medically appropriate type of setting or level of care available.

Exclusion means that items or services furnished or ordered by a specified health care practitioner, provider, or other person during a specified period are not reimbursed under Medicare.

Gross and flagrant violation means a violation of an obligation has occurred in one or more instances which presents an imminent danger to the health, safety or well-being of a Medicare beneficiary or places the beneficiary unnecessarily in high-risk situations.

Health care services or *Services* means services or items for which payment may be made (in whole or in part) under the Medicare program.

Obligation means any of the obligations specified at section 1156(a) of the Act.

OIG stands for the Office of the Inspector General, Department of Health and Human Services.

Other person means a hospital or other health care facility, an organization, or an agency that furnishes health care services for which payment may be made under the Medicare program.

Physician means a doctor of medicine or osteopathy or another individual who is authorized under State or Federal law to practice medicine and surgery or osteopathy.

Practitioner means a physician or other health care professional licensed under State law to practice his or her profession.

PRO area means the geographic area subject to review by a particular PRO.

Provider means a hospital or other health care facility, agency, or organization.

Sanction means an exclusion or monetary penalty that the Secretary may impose on a practitioner or other person as a result of a recommendation from a PRO.

Substantial violation in a substantial number of cases means a pattern of care has been provided that is inappropriate, unnecessary, or does not meet recognized professional standards of care, or is not supported by the necessary documentation of care as required by the PRO.

Subpart B—Sanctions Under the PRO Program; General Provisions

§ 1004.10 Statutory obligations of practitioners and other persons.

It is the obligation of any health care practitioner or other person who furnishes or orders health care services that may be reimbursed under Medicare, to ensure, to the extent of his or her authority, that those services are—

(a) Furnished economically and only when and to the extent medically necessary;

(b) Of a quality that meets professionally recognized standards of health care; and

(c) Supported by evidence of the medical necessity and quality of the services in the form and fashion that the reviewing PRO may reasonably require (including copies of the necessary documentation and evidence of compliance with pre-admission or pre-procedure review requirements to ensure that the practitioner or other person is meeting the obligations imposed by section 1156(a) of the Act.

§ 1004.20 Sanctions.

In addition to any other sanction provided under law, a practitioner or other person may be—

(a) Excluded from Medicare; or

(b) In lieu of exclusion and as a condition for continued participation in Medicare, if the violation involved the provision or ordering of health care services that were medically improper or unnecessary, required to pay an amount not in excess of the cost of the improper or unnecessary services that were furnished or ordered. The practitioner or other person will be required either to pay the monetary assessment within 6 months of the date of notice or have it deducted from any sums the Federal Government owes the practitioner or other person.

Subpart C—PRO Responsibilities

§ 1004.30 Basic responsibilities.

(a) The PRO must use its authority or influence to enlist the support of other professional or government agencies to ensure that each practitioner or other person complies with the obligations specified in § 1004.10.

(b) The PRO must identify situations where the obligations specified in § 1004.10 are violated and afford the practitioner or other person reasonable notice and opportunity for discussion in accordance with §§ 1004.40 and 1004.50.

(c) The PRO must submit a report to the OIG after the notice and opportunity provided under paragraph (b) of this section, if the PRO determines that the practitioner or other person has—

(1) Failed substantially to comply with any obligation in a substantial number of cases; or

(2) Grossly and flagrantly violated any obligation in one or more instances.

(d) The PRO report to the OIG must comply with the provisions of § 1004.70.

(e) The PRO must deny services or items ordered by an excluded practitioner or other person when the PRO identifies the services or items and reports the findings to HCFA.

§ 1004.40 Action on identification of a violation.

When a PRO identifies a violation, it must determine the nature of the violation.

(a) If the PRO determines the violation as one that is gross and flagrant, it must proceed in accordance with § 1004.50.

(b) If the PRO determines the violation as a substantial violation in a substantial number of cases it must send the practitioner or other person a written initial notice of the identification of a violation containing the following information:

(1) The obligation involved.

(2) The situation, circumstances, or activity that resulted in a violation.

(3) The authority and responsibility of the PRO to report violations of obligations.

(4) At the discretion of the PRO, a suggested method for correcting the situation and a time period for corrective action.

(5) The sanction that the PRO could recommend to the OIG if the violation continues.

(6) An invitation to submit additional information to or discuss the problem with representatives of the PRO within 20 days of receipt of the notice. The date of receipt is presumed to be five days after the date on the notice, unless there is a reasonable showing to the contrary.

(7) A summary of the information used by the PRO in arriving at its determination of a violation of an obligation.

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§ 1004.50 Action on determination of a violation.

(a) *Written notice.* The PRO must give written notice to the practitioner or other person if it determines that—

(1) A substantial violation has occurred in a substantial number of cases; or

(2) A violation is gross and flagrant in one or more cases.

(b) *Contents.* The notice must contain the following information:

(1) The determination of a violation.

(2) The obligation violated.

(3) The basis for the determination.

(4) The sanction the PRO will recommend to the OIG.

(5) The right of the practitioner or other person to submit to the PRO within 30 days of receipt of the notice, additional information or a written request for a meeting with the PRO to review and discuss the determination, or both. The date of receipt is presumed to be five days after the date on the notice, unless there is a reasonable showing to the contrary.

(6) A copy of the material used by the PRO in arriving at its determination.

(c) *Review of PRO determination.*

(1) The PRO may, on the basis of additional information received, affirm, modify, or reverse its determination.

(2) The PRO must give written notice to the practitioner or other person, of any action it takes as a result of the additional information received, as specified in § 1004.60

(Approved by the Office of Management and Budget under control number 0938-0444)

§ 1004.60 Final PRO determination of a violation.

If the issue is not resolved to the PRO's satisfaction as specified in § 1004.50(c), the PRO must—

(a) Submit its report and recommendation to the OIG; and

(b) Send the affected practitioner or other person a concurrent final notice, with a copy of the PRO report that is being forwarded to the OIG, advising that—

(1) The PRO recommendation has been submitted to the OIG;

(2) The practitioner or other person has 30 days from receipt of this final notice to submit any additional written material or documentary evidence to the OIG at its central office location. The date of receipt is presumed to be five days after the date on the notice, unless there is a reasonable showing to the contrary; and

(3) Due to the 120-day statutory requirement specified at § 1004.90(e), the period for submitting additional information will not be extended and any material received by the OIG after the 30-day period will not be considered.

(Approved by the Office of Management and Budget under control number 0938-0444)

§ 1004.70 PRO report to OIG.

(a) *Manner of reporting.* If the PRO determines that a substantial violation has occurred in a substantial number of cases or that a gross and flagrant violation has occurred, it must submit a report and recommendation to the OIG at the regional office with jurisdiction.

(b) *Content of report.* The PRO report must include the following information—

(1) Identification of the practitioner or other persons and when applicable, the name of the director, administrator, or owner of the entity involved;

(2) The type of health care services involved;

(3) A description of each failure to comply with an obligation, including

specific dates, places, circumstances, and any other relevant facts;

(4) Pertinent documentary evidence;

(5) Copies of written correspondence and written summaries of oral exchanges with the practitioner or other person regarding the violation;

(6) The PRO's determination that an obligation under section 1156(a) of the Act has been violated and that the violation is substantial and has occurred in a substantial number of cases or is gross and flagrant;

(7) The professional qualifications of the PRO's reviewers' and

(8) The PRO's sanction recommendation.

(c) *PRO Recommendation.* The PRO must specify in its report—

(1) The sanction recommended;

(2) The amount of the monetary penalty recommended, if applicable;

(3) The period of exclusion recommended, if applicable; and

(4) A recommendation as to whether the practitioner or other person is unable or unwilling substantially to comply with the obligation that was violated.

(Approved by the Office of Management and Budget under control number 0938-0444)

§ 1004.80 Basis for recommended sanction.

The PRO's specific recommendation must be based on a consideration of—

(a) The type of offense involved:

(b) The severity of the offense;

(c) The deterrent value;

(d) The practitioner's or other person's previous sanction record;

(e) The availability of alternative sources of services in the community; and

(f) Any other factors that the PRO considers relevant (for example, the duration of the problem).

Subpart D—OIG Responsibilities

§ 1004.90 Acknowledgement and review of report.

(a) *Acknowledgement.* The OIG will inform the PRO of the date it received the PRO's report and recommendation.

(b) *Review.* The OIG will review the PRO report and recommendation to determine whether—

(1) The PRO is following its procedures;

(2) A violation has occurred; and

(3) The practitioner or other person has demonstrated an unwillingness or lack of ability substantially to comply with an obligation.

(c) *Rejection of the PRO recommendation.* If the OIG decides that a sanction is not warranted, it will notify the PRO that recommended the sanction and the affected practitioner or other person that the recommendation is rejected.

(d) *Decision of sanction.* If the OIG decides that a violation of obligations has occurred, it will determine the appropriate sanction by considering—

(1) The recommendation of the PRO;

(2) The type of offense;

(3) The severity of the offense;

(4) The previous sanction record of the practitioner or other person;

(5) The availability of alternative sources of services in the community;

(6) Any prior problems the Medicare carrier or intermediary has had with the practitioner or other person;

(7) Whether the practitioner or other person is unable or unwilling to comply substantially with the obligations; and

(8) Any other matters relevant to the particular case.

(e) *Exclusion sanction.* If the PRO submits a recommendation for exclusion to the OIG, and a determination is not made by the 120th day after actual receipt by the OIG, the exclusion sanction recommended will become effective and the OIG will provide notice in accordance with § 1004.100(f).

(f) *Monetary penalty.* If the PRO recommendation is to assess a monetary penalty, the 120-day provision does not apply and the OIG will provide notice in accordance with § 1004.100 (a) through (e).

§ 1004.100 Notice of sanction.

(a) The OIG notifies the practitioner or other person of the adverse determination and of the sanction to be imposed.

(b) The sanction is effective 15 days from the date of receipt of the notice. The date of receipt is presumed to be 5 days after the date on the notice, unless there is a reasonable showing to the contrary.

(c) The notice specifies—

(1) The legal and factual basis for the determination:

(2) The sanction to be imposed;

(3) The effective date and, if appropriate, the duration of the exclusion;

(4) The appeal rights of the practitioner or other person; and

(5) In the case of exclusion, the earliest date on which the OIG will accept a request for reinstatement.

(d) The OIG notifies the public by publishing in a newspaper of general circulation in the PRO area a notice that identifies the sanctioned practitioner or other person, the obligation that has been violated, the sanction imposed and, if the sanction is exclusion, the effective date and duration.

(e) Notice of the sanction is also provided to the following entities as appropriate:

(1) The PRO that originated the sanction report.

(2) PROs in adjacent areas.

(3) State Medicaid fraud control units and State licensing bodies.

(4) Appropriate Medicare contractors and State agencies.

(5) Hospitals, including the hospital where the sanctioned individual's case originated and where the individual currently has privileges, if known; skilled nursing facilities, home health agencies, and health maintenance organizations (HMOs).

(6) Medical societies and other professional organizations.

(7) Medical carriers and intermediaries, health care prepayment plans, and other affected agencies and organizations.

(f) If an exclusion sanction is effected because a decision was not made within 120 days after receipt of the PRO recommendation, notification is as follows:

(1) The OIG notifies the practitioner or other person that the exclusion from the Medicare program is effective 15 days from the date the notice is received by the practitioner or other person. The date of receipt is presumed to be five days after the date on the notice, unless there is a reasonable showing to the contrary.

(2) Notice of the sanction is also provided as specified in paragraph (e) of this section.

(3) As soon as possible after the 120th day, the OIG will issue a notice to the practitioner or other person affirming the PRO recommendation or modifying the recommendation based on the OIG's review of the case.

(g) The determination and notice of sanction provided for in this section constitute an "initial determination" and a "notice of initial determination" for purposes of the administrative appeals procedures specified in Part 498 of this title concerning determinations and appeals procedures for providers and suppliers.

[51 FR 34783, Sept. 30, 1986, as amended at 52 FR 22454, June 12, 1987]

Subpart E—Effect and Duration of Exclusion

§ 1004.110 Effect of an exclusion on Medicare payments and services.

(a) *General provisions.* Except as provided under paragraphs (b) and (c) of this section—

(1) Payment will not be made under Medicare to an excluded practitioner or other person for services or items furnished or ordered during the period of exclusion;

(2) Payment will not be made under Medicare to any provider for services or items ordered by an excluded practitioner or other person when the order was a necessary precondition for payment under Medicare; and

(3) Assignment of a beneficiary's claim for services or items furnished or ordered by an excluded practitioner or other person on or after the effective date of exclusion will not be valid.

(b) *Exceptions.* Payment is available for services or items provided up to 30 days after the effective date of an exclusion for—

(1) Inpatient hospital or skilled nursing services or items furnished to a beneficiary who was admitted before

the effective date of the exclusion; and

(2) Home health services or items furnished under a plan established before the effective date of the exclusion.

(c) *Denial of payments to beneficiaries.* If a beneficiary submits claims for services or items furnished or ordered by an excluded practitioner or other person on or after the effective date of exclusion—

(1) HCFA pays the first claim submitted and immediately gives the beneficiary notice of the exclusion; and

(2) The beneficiary's right to payment extends to services or items furnished or ordered up to 15 days after the date on the notice.

(d) *Effective date of termination of provider agreement.* The effective date of termination of a Medicare provider agreement is determined in accordance with §§ 1001.201 and 1001.211 of this chapter.

§ 1004.120 Reinstatement after exclusion.

Exclusion will remain in effect until—

(a) The OIG determines, in accordance with §§ 1001.130 through 1001.136 of this chapter, that the basis for the exclusion no longer exists and there is reasonable assurance that the problems will not recur, or

(b) The OIG's determination to exclude is reversed by a hearing decision.

Subpart F—Appeals

§ 1004.130 Appeal rights.

(a) *Right to administrative review.*

(1) A practitioner or other person dissatisfied with an OIG determination or an exclusion that results from a determination not being made within 120 days is entitled to a hearing before an Administrative Law Judge and may also request a review of that decision by the Appeals Council in accordance with Part 498 of this title.

(2) Due to the 120-day statutory requirement specified at § 1004.90(e) of this part, the following limitations apply:

(i) The period for submitting additional information will not be extended.

(ii) Any material received by the OIG after the 30-day period allowed, will not be considered and will not be subject to review by the Administrative Law Judge and the Appeals Council.

(3) The OIG's determination continues in effect unless reversed by a hearing decision.

(b) *Right to judicial review.* Any practitioner or other person dissatisfied with a decision of the Appeals Council or an administrative law judge (if a request for Appeals Council review is denied) may file a civil action in accordance with the provisions of section 205(g) of the Act.

[51 FR 34783, Sept. 30, 1986, as amended at 52 FR 22454, June 12, 1987]

FINDING AIDS

A list of CFR titles, subtitles, chapters, subchapters and parts and an alphabetical list of agencies publishing in the CFR are included in the CFR Index and Finding Aids volume to the Code of Federal Regulations which is published separately and revised annually.

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ANSI A117.1-1971 Specifications for Making Buildings and Facilities Accessible to and Usable by Physically Handicapped People.	442.330(a)(2) and (b)
National Academy of Sciences	
Academy Press, 2101 Constitution Ave., NW., Washington, DC 20418	
Recommended Dietary Allowances Current Edition, 1980 (9th Ed.)	442.332(a)(1); 442.466(c)
National Fire Protection Association	
Batterymarch Park, Quincy, MA 02269	
NFPA Standard No. 101, Life Safety Code 1981	442.321(a)
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Small Business Administration	13, I; 48, 22
Smithsonian Institution	36, V
Social Security Administration	20, III; 45, IV
Soil Conservation Service	7, VI
Solar Energy and Energy Conservation Bank, Department of Housing and Urban Development	24, XI
Soldiers' and Airmen's Home, United States	5, XI

Agency	CFR Title, Subtitle or Chapter
Special Education and Rehabilitative Services, Office of	34, III
State Department	22, I
Federal Acquisition Regulation	48, 6
Surface Mining and Reclamation Appeals, Board of	30,III
Susquehanna River Basin Commission	18, VIII
Tennessee Valley Authority	18, XIII
Trade Representative, United States, Office of	15, XX
Transportation, Department of	44, IV
Coast Guard	33, I; 46, I, III; 49, IV
Commercial Space Transportation, Office of	14, III
Contract Appeals Board	48, 63
Federal Acquisition Regulation	48, 12
Federal Aviation Administration	14, I
Federal Highway Administration	23, I, II; 49, III
Federal Railroad Administration	49, II
Maritime Administration	46, II
National Highway Traffic Safety Administration	23, II, III; 49, V
Research and Special Programs Administration	49, I
Saint Lawrence Seaway Development Corporation	33, IV
Secretary of Transportation, Office of	14, II; 49, Subtitle A
Urban Mass Transportation Administration	49, VI
Transportation, Office of, Department of Agriculture	7, XXXIII
Travel Service, United States	15, XII
Treasury Department	17, IV
Alcohol, Tobacco and Firearms, Bureau of	27, I
Comptroller of the Currency	12, I
Customs Service, United States	19, I
Engraving and Printing, Bureau of	31, VI
Federal Acquisition Regulation	48, 10
Federal Law Enforcement Training Center	31, VII
Fiscal Service	31, II
Foreign Assets Control, Office of	31, V
Internal Revenue Service	26, I
Monetary Offices	31, I
Secret Service	31, IV
Secretary of the Treasury, Office of	31, Subtitle A
United States Customs Service	19, I
Truman, Harry S. Scholarship Foundation	45, XVIII
United States and Canada, International Joint Commission	22, IV
United States Arms Control and Disarmament Agency	22, VI
United States Customs Service	19, I
United States Fish and Wildlife Service	50, I, IV
United States Information Agency	22, V; 48, 19
United States International Development Cooperation Agency	22, XII
United States International Trade Commission	19, II
United States Postal Service	39, I
United States Soldiers' and Airmen's Home	5, XI
United States Trade Representative, Office of	15, XX
United States Travel Service	15, XII
Urban Mass Transportation Administration	49, VI
Veterans Administration	38, I; 48, 8
Veterans Employment and Training, Office of the Assistant Secretary for	41, 61
Vice President of the United States, Office of	32, XXVIII
Vocational and Adult Education, Office of	34, IV
Wage and Hour Division	29, V
Water Resources Council	18, VI
Workers' Compensation Programs, Office of	20, I
World Agriculture Outlook Board	7, XXXVIII

Table of OMB Control Numbers

The OMB control numbers for Chapter IV of Title 42 appear in § 400.310. Sections 400.300 and 400.310 are reprinted below for the convenience of the user.

Subpart C—OMB Control Numbers for Approved Collections of Information

SOURCE: 49 FR 4477, Feb. 7, 1984, unless otherwise noted.

§ 400.300 Scope.

This subpart collects and displays control numbers assigned by the Office of Management and Budget (OMB) to collections of information contained in HCFA regulations, in accordance with OMB's regulations for controlling paperwork burdens on the public, 5 CFR Part 1320. HCFA intends that the subpart comply with the requirements of section 3507(f) of the Paperwork Reduction Act of 1980, 44 U.S.C. Chapter 35 which requires that agencies shall not engage in a "collection of information" without obtaining a control number from OMB.

§ 400.310 Display of currently valid OMB control numbers.

Sections in 42 CFR that contain collections of information	Current OMB control numbers
403.232, 403.239–403.258	0938–0264
403.304, 403.306, 403.312, 403.316, 403.318 and 403.320–403.322	0938–0473
405.165, 405.170	0938–0454
405.262	0938–0267
405.334, 405.336	0938–0465
405.481	0938–0285
405.552	0938–0285
405.1121–405.1128, 405.1136, 405.1137	0938–0364
405.1201, 405.1202, 405.1221, 405.1223–405.1226, 405.1228, 405.1229	0938–0365
405.1315, 405.1317	0938–0368
405.1413, 405.1414, 405.1416	0938–0338
405.1627, 405.1629	0938–0308
405.1632	0938–0454
405.1716, 405.1717, 405.1720, 405.1721, 405.1722, 405.1725, 405.1736	0938–0336
405.2112, 405.2123, 405.2136–405.2140, 405.2171	0938–0386
412.44	0938–0445
412.71	0938–0288
412.92	0938–0308 and 0938–0477
412.118	0938–0337 and 0938–0456
413.30	0938–0337
416.47	0938–0266
417.412–417.414, 417.418, 417.424, 417.426, 417.428, 417.430, 417.432, 417.436, 417.444, 417.446, 417.454, 417.460, 417.474, 417.476, 417.478, 417.480, 417.481, 417.486, 417.488, 417.492, 417.494, 417.520, 417.522, 417.532, 417.548, 417.560, 417.566, 417.568, 417.570, 417.572, 417.576, 417.586, 417.592, 417.594, 417.596–417.598, 417.604, 417.608, 417.616, 417.620, 417.624, 417.632, 417.650, 417.662, 417.690, 417.801, 417.808, 417.810	0938–0406
418.22, 418.26, 418.56, 418.58, 418.70, 418.74, 418.83, 418.100	0938–0302 and 0938–0476
430.30	0938–0067 and 0938–0101
431.17	0938–0467
431.55	0938–0295
431.306	0938–0467 and 0938–0502
431.630	0938–0445
431.800	0938–0431
432.50	0938–0459
433.112	0990–0058 and 0938–0247
433.116	0938–0247 and 0938–0442
433.117	0990–0058 and 0938–0247
433.138	0938–0502
433.139	0938–0459
434.6–434.20, 434.23–434–27, 434.30, 434.32, 434.36, 434.50, 434.53, 434.55	0938–0326
435.910, 435.919, 435.920, 435.940	0938–0467

Sections in 42 CFR that contain collections of information	Current OMB control numbers
435.945	0938-0467 and 0938-0502
435.948, 435.952, 435.955	0938-0467
435.960	0938-0467 and 0938-0502
435.965	0938-0467
441.56, 441.58, 441.60, 441.61	0938-0354
441.255-441.259	0938-0481
441.301	0938-0449
441.302	0938-0268 and 0938-0449
441.303	0938-0272 and 0938-0449
442.118	0938-0488
442.307, 442.308, 442.309, 442.311, 442.313, 442.314, 442.318, 442.319, 442.320	0938-0370
442.402, 442.404-442.407, 442.412, 442.413, 442.417, 442.421, 442.423-442.425, 442.427, 442.430, 442.434, 442.441, 442.443, 442.457, 442.460, 442.463, 442.466, 442.468, 442.475, 442.482-442.487, 442.490, 442.492, 442.497, 442.500-442.503, 442.505, 442.506, 442.512	0938-0366
447.30	0938-0067
447.31	0938-0287
447.53	0938-0429
447.253(a)	0938-0193
447.255	0938-0193
456.654	0938-0445
466.70, 466.72, 466.74, 466.78, 466.80, 466.94	0938-0445
473.18, 473.34, 473.36, 473.42	0938-0443
474.36, 474.38-474.40	0938-0444
476.104, 476.105, 476.116, 476.134	0938-0428
482.12, 482.22, 482.27, 482.30, 482.41, 482.53, 482.56, 482.57 and 482.60-482.62	0938-0328
488.56, 488.60, 488.64	0938-0267
498.22, 498.40, 498.58, 498.82	0938-0508

[53 FR 16268, May 6, 1988; 53 FR 21762, June 9, 1988, as amended at 53 FR 36571, Sept. 21, 1988]

EFFECTIVE DATE NOTE: At 53 FR 36571, Sept. 21, 1988, § 400.310 was amended by adding "430.30" and its corresponding OMB control numbers "0938-0067" and "0938-0101" to the table, effective October 21, 1988.

Redesignation Table I

At 42 FR 52826, September 30, 1977, regulations formerly appearing in Title 42 as Part 101 were redesignated and transferred into Parts 460 through 480 of this title.

For the convenience of the user, the following table shows the relationship of the redesignated sections.

New section	Old section
460.1	101.1
460.2	101.2
460.2a	101.2a
460.3	101.3
460.4	101.4
460.5	101.5
460.6	101.6
460.7	101.7
460.8	101.8
460.9	101.9
460.10	101.10
460.11	101.11
460.12	101.12
460.13	101.13
460.14	101.14
460.15	101.15
460.16	101.16
460.17	101.17
460.18	101.18
460.19	101.19
460.20	101.20
460.21	101.21
460.22	101.22
460.23	101.23
460.24	101.24
460.25	101.25
460.26	101.26
460.27	101.27
460.28	101.28
460.29	101.29
460.30	101.30
460.31	101.31
460.32	101.32
460.33	101.33
460.34	101.34
460.35	101.35
460.36	101.36
460.37	101.37
460.38	101.38
460.39	101.39
460.40	101.40
460.41	101.41
460.42	101.42
460.43	101.43
460.44	101.44
460.45	101.45
460.46	101.46
460.47	101.47
460.48	101.48
460.49	101.49
460.50	101.50
460.51	101.51
460.52	101.52
460.53	101.53
460.54	101.54
460.55	101.55
460.56	101.56
461.1	101.101
461.2	101.102
461.3	101.103
461.4	101.104
461.5	101.105
461.6	101.106
461.7	101.107
473.1	101.1401
473.2	101.1402
473.3	101.1403
473.4	101.1404
473.5	101.1405
473.6	101.1406
480.1	101.2101
480.2	101.2102
480.3	101.2103
480.4	101.2104
480.5	101.2105
480.6	101.2106

Redesignation Table II

At 42 FR 52827, September 30, 1977, regulations formerly appearing in Title 45 as Parts 246, 248, 249, 250, 251 and 252 were redesignated and transferred into Title 42 as Parts 446, 448, 449, 450, 451 and 452, respectively.

For the convenience of the user, the following table shows the relationship of the redesignated sections.

New section (Title 42)	Old section (Title 45)	New section (Title 42)	Old section (Title 45)
446.10	246.10	449.70	249.7
446.160	246.160	449.81	249.8
448.1	248.1	449.82	249.8
448.2	248.2	450.18	250.1
448.3	248.3	450.19	250.1
448.4	248.4	450.20	250.2
448.10	248.10	450.21	250.2
448.11	248.11	450.23	250.2
448.21	248.21	450.24	250.2
448.30	248.30	450.25	250.2
448.40	248.40	450.30	250.3
448.50	248.50	450.31	250.3
448.60	248.60	450.41	250.4
448.70	248.70	450.70	250.7
448.80	248.80	450.71	250.7
449.10	249.10	450.80	250.8
449.12	249.12	450.90	250.9
449.13	249.13	450.100	250.10
449.20	249.20	450.120	250.12
449.31	249.31	450.210	250.21
449.32	249.32	450.220	250.22
449.33	249.33	451.10	251.1
449.40	249.40	452.10	252.1
449.41	249.41		

Redesignation Table III

The following regulations were reorganized and redesignated at 43 FR 45176, September 29, 1978. For the convenience of the user, the following tables show the relationship of the redesignated sections.

PART 446

Old section	New section
446.10	431.12
446.151	432.2
446.160	432.10
446.165	432.31
446.166	432.32
446.170	432.30
446.175	432.50
446.180	432.55
446.185	432.60

PART 448

Old section	New section
Beginning note	435.2.
448.1(a)(1)(i)	435.4.
448.1(a)(1)(ii)	435.732.
448.1(a)(1)(ii)(A)	435.321.
448.1(a)(1)(ii)(B)	435. Unnecessary.
448.1(a)(2)(i)	435.4.
448.1(a)(2)(ii)	435.831.
448.1(a)(3)	435.740.
448.1(b) first sentence	435.10.
448.1(b)(1)(i)	435.110.
448.1(b)(1)(ii)	435.111.
448.1(b)(1)(iii)	435.112.
448.1(b)(2)	Unnecessary.
448.1(b)(2)(i)	435.120.
448.1(b)(2)(ii)	435.230.
448.1(b)(2)(iii)	435.121.
448.1(b)(2)(iv)	435.130.
448.1(b)(2)(v)	435.131.
448.1(b)(2)(vi)except (B)	435.132.
448.1(b)(2)(vi)(B)	Redundant with 435.132 first sentence.
448.1(b)(2)(vii)	435.133.
448.1(b)(2)(viii) words before "In States"	Unnecessary.
448.1(b)(2)(viii)	435.135.
448.1(b)(3) introductory sentence	Unnecessary.
448.1(b)(3)(i)	435.113, 435.122.
448.1(b)(3)(ii)	435.114, 435.134.
448.1(c) first sentence	435.10, 435.200.
448.1(c)(1)	435.210.
448.1(c)(2) except second sentence	435.211.
448.1(c)(2) second sentence	Unnecessary.
448.1(c)(3)	435.223.
448.1(c)(4)	435.222.

PART 448—Continued

Old section	New section
448.1(c)(5)	435.221.
448.1(c)(6)	435.220.
448.1(d)(1)	435.301.
448.1(d)(2)	435.325.
448.1(e)	435.10.
448.2(a)	435.401.
448.2(b)(1)	435.501.
448.2(b)(2)	Unnecessary.
448.2(c)	435.401.
448.2(d)	435.230.
448.2(e) words before " if a State plan.	Unnecessary.
448.2(e) words after "Notwithstanding the provisions specified in paragraph (d) of the section "	435.231, 435.722.
448.3(a)(1)	435.10.
448.3(a)(1)(i)	435.711.
448.3(a)(1)(ii)(A)	435.721(a).
448.3(a)(1)(ii)(B)(*1*)	435.721(a).
448.3(a)(1)(ii)(B)(*2*), words before "provided that"	435.721(b).
448.3(a)(1)(ii)(B)(*2*), words beginning "provided that"	435.1006.
448.3(a)(1)(ii)(C), first sentence	435.10.
448.3(a)(1)(ii)(C), second sentence.	435.121(b).
448.3(a)(2)	Unnecessary.
448.3(b)(1)	Unnecessary.
448.3(b)(1)(i) first sentence	Unnecessary.
448.3(b)(1)(i) second sentence	435.723(b).
448.3(b)(1)(i) third sentence	435.712(a), 435.724(b).
448.3(b)(1)(i) fourth sentence	435.724(b).
448.3(b)(1)(ii)	435.603.
448.3(b)(1)(iii)	435.602.
448.3(b)(2)(i)	435.723(c).
448.3(b)(2)(ii)	435.723(d).
448.3(b)(2)(iii)	435.721(c).
448.3(b)(2)(iv) first sentence	435.831(a)(2).
448.3(b)(2)(iv) second sentence	Unnecessary.
448.3(o)(2)(iv) third sentence words before " after deducting all "	435.811.
448.3(b)(2)(iv) third sentence words after " to the assistance unit "	435.831(c).
448.3(b)(3)(i)	435.724(b).
448.3(b)(3)(ii)	435.724(c).
448.3(b)(3)(iii)	435.724(c).
448.3(b)(3)(iv)	435.721(c).

PART 448—Continued

Old section	New section
448.3(b)(3)(v) first sentence words before ". . . except that the income . . .".	435.721(c).
448.3(b)(3)(v) first sentence words after ". . . medically needy determinations . . .".	Unnecessary.
448.3(b)(3)(v) second sentence words before ". . . after deducting all . . .".	435.811.
448.3(b)(3)(v) second sentence words after ". . . to the assistance unit . . .".	435.831(c).
448.3(b)(4) first paragraph	435.734.
448.3(b)(4) second paragraph	Unnecessary.
448.3(b)(5)(i)	435.712(a).
448.3(b)(5)(ii)	435.712(c).
448.3(b)(5)(iii)	435.712(b).
448.3(b)(5)(iv) first sentence	Unnecessary.
448.3(b)(5)(iv) second sentence words before ". . . to the assistance unit . . .".	435.811.
448.3(b)(5)(iv) second sentence words after ". . . to the assistance unit . . .".	435.831(c).
448.3(b)(6)	435.404.
448.3(b)(7)	435.725, 435.731, 435.733, 435.813, 435.815, 435.832.
448.3(b)(8)	435.725, 435.732, 435.733, 435.832.
448.3(b)(9)	435.732.
448.3(c)(1)	Unnecessary.
448.3(c)(1)(i)	435.811.
448.3(c)(1)(ii)	435.812(a), 435.814(a), 435.816(a).
448.3(c)(1)(ii)(A)	435.816.
448.3(c)(1)(ii)(B) words before "except that".	435.812, 435.814.
448.3(c)(1)(ii)(B) words beginning "except that".	Unnecessary.
448.3(c)(1)(iii)	435.812(b), 435.814(b).
448.3(c)(1)(iv) words before "and the amount of liquid . . .".	435.834, 435.835.
448.3(c)(1)(iv) words after ". . . of the Social Security Act . . ." and before ". . . except that . . .".	435.834(c), 435.835(c).
448.3(c)(1)(iv) words after ". . . in a family . . ." to end of sentence.	435.834(b).
448.3(c)(1)(iv) last sentence	Unnecessary.
448.3(c)(2)	435.831.
448.3(c)(3) first sentence	Redundant.
448.3(c)(3)(i)	435.831(a)(1), 435.841(c).
448.3(c)(3)(ii)	435.831(a)(2), (3), 435.841(d), (e).
448.3(c)(4)	435.831(a), 435.841(b).
448.4(a)	435.1001.
448.4(b)(1)	435.1002.
448.4(b)(1)(i)	Unnecessary.
448.4(b)(1)(ii)	Unnecessary.
448.4(b)(1)(iii)	Unnecessary.
448.4(b)(2)	435.1008.
448.4(b)(3) first sentence	435.1005 and 435.1006.
448.4(b)(3) second sentence	Unnecessary.
448.4(b)(4)	435.1007.
448.4(b)(5)	435.1002(b).
448.4(b)(6)	435.1004.
448.4(b)(7) except last sentence	435.1003.
448.4(b)(7) last sentence	Unnecessary.
448.4(b)(8)	Unnecessary.
448.4(c)	Unnecessary.
448.4(d)	435.1010.
448.4(e)	435.1011.
448.10(a)	Unnecessary.
448.10(b)(1)(i)	436.110.
448.10(b)(1)(ii)	436.115.
448.10(b)(1)(iii)	436.111.
448.10(b)(2)(i)	436.210.
448.10(b)(2)(ii)	436.211.
448.10(b)(2)(iii)	436.212.
448.10(b)(2)(iv)	436.222.
448.10(b)(2)(v)	436.221.
448.10(b)(2)(vi)	436.220.
448.10(b)(3)	436.112.
448.10(b)(4)	436.116.
448.10(b)(5) 1st sentence	436.301, 436.310, 436.320, 436.330.
448.10(b)(5) 2d sentence	Unnecessary.
448.10(b)(6)	436.10.
448.10(b)(7)	Obsolete.
448.10(c)(1)	436.401(b).
448.10(c)(2)	Obsolete.
448.10(c)(3)	436.401(c).
448.10(c)(4)	436.401(a).
448.10(c)(5)	436.602.
448.10(d)(1)	436.1001(a), 436.1002(a).
448.10(d)(2) except undesignated paragraph after.	Unnecessary.
448.10(d)(2) undesignated paragraph after (vi).	436.1004(a).
448.10(d)(3)	436.1002(b).
448.10(d)(4)	436.1003.
448.11	436.230.
448.21(a)(1)(i)	436.711.
448.21(a)(1)(ii)	Redundant.
448.21(a)(2)(i)(A)–(C) 1st sentence except words before "and amounts received".	Redundant.
448.21(a)(2)(i)(C) 1st sentence, words after "applicant or recipient", and 2d sentence.	436.603.
448.21(a)(2)(ii)	436.602.
448.21(a)(2)(iii)	Redundant.
448.21(a)(2)(iv)	436.711.
448.21(a)(2)(v)	436.711.
448.21(a)(2)(vi)	436.404.
448.21(a)(3)(i) introductory paragraph.	Unnecessary.
448.21(a)(3)(i)(A)	436.811.
448.21(a)(3)(i)(B)	436.812.
448.21(a)(3)(i)(C) 1st and 2d sentences.	436.813.
448.21(a)(3)(i)(C) 3rd–4th sentences.	436.832.
448.21(a)(3)(i)(D) 1st sentence	436.840.
448.21(a)(3)(i)(D) last sentence	Unnecessary.
448.21(a)(1)(ii)–(iv)	436.831.
448.21(b)	Redundant.
448.21(c)	436.1002.
448.30(a), (b)(2) and (3)	435.520, 436.520.
448.30(b)(1) 1st sentence	Redundant with 435.1002.
448.30(b)(1) 2d sentence	Unnecessary.
448.40(a)(1) words before "but are absent", and (b)(1) and (2).	435.403, 436.403.
448.40(a) words after "residents of the State".	431.52.
448.40(b) introductory paragraph	Redundant with 435.403(a).

PART 448—Continued

Old section	New section
448.50	435.402, 436.402.
448.60(a)(1)–(3)(i) and (iv)	435.1008, 436.1004.
448.60(a)(3)(ii) except "or mental diseases".	435.1009 "institution for tuberculosis".
448.60(a)(3)(ii) except "tuberculosis or".	435.1009 "institution for mental diseases".
448.60(a)(3)(iii)	435.1009 "institution for mental diseases".
448.60(b)(1)–(11)	435.1009, 436.1005.
448.70(a)(1) words before "and in Guam".	435.530.
448.70(a)(1) words after parenthetical note.	436.530.
448.70(a)(2)(i) and (ii) 1st sentence.	435.531(a)(1) and (2), 436.531(a) and (b).
448.70(a)(2)(ii) 2d sentence	435.531(a)(3), 436.531(c).
448.70(a)(3)	435.531(a)(3), 436.531(c).
448.70(b)	435.531(b).
448.70(c)(1) 1st sentence	Redundant with 435.1002.
448.70(c)(1) 2d sentence	435.531(a)(3)(ii).
448.70(c)(1) parenthetical note	435.1003.
448.70(c)(2)	435.1001(b), 436.1001(b).
448.80(a)(1) words before "and in Guam".	435.540.
448.80(a)(1) words after parenthetical note.	436.540.
448.80(a)(2) and (b)	435.541, 436.541.
448.80(c)(1) 1st sentence	Redundant with 435.1002.
448.80(c)(1) 2d sentence	435.541(c).
448.80(c)(2)	435.1001(b), 436.1001(b).

PART 449

Old section	New section
449.10(a)(1)	440.210.
449.10(a)(2)	440.220.
449.10(a)(3) introductory paragraph.	441.51.
449.10(a)(3)(i)	441.54.
449.10(a)(3)(ii)	441.55.
449.10(a)(3)(iii)	441.56.
449.10(a)(3)(iv)	441.53.
449.10(a)(4)	441.15.
449.10(a)(5)(i)	440.230.
449.10(a)(5)(ii)	431.53.
449.10(a)(6) introductory paragraph.	440.240.
449.10(a)(6)(i)–(vii)	440.250.
449.10(a)(7)	440.240.
449.10(a)(8)	440.260.
449.10(a)(9)	441.20.
449.10(a)(10)	441.30.
449.10(a)(11)	431.110, 442.201(c), 442.251(d).
449.10(b) introductory paragraph	440.2.
449.10(b)(1)	440.10.
449.10(b)(2)	440.20.
449.10(b)(3)	440.30.
449.10(b)(4)(i)(A)	440.40.
449.10(b)(4)(i)(B)	442.201(a), (b).
449.10(b)(4)(i)(C) 1st sentence, words before "except that with".	440.40.
449.10(b)(4)(i)(C) 1st sentence, words after "payments under the plan".	441.11.
449.10(b)(4)(i)(C) 2d and 3d sentences.	412.30.
449.10(b)(4)(ii) 1st sentence	440.40.
449.10(b)(4)(ii) 2d and 3d sentences.	441.52.
449.10(b)(5)	440.50.
449.10(b)(6)	440.60.
449.10(b)(7) except (i) introductory paragraph, last sentence.	440.70.
449.10(b)(7)(i) introductory paragraph, last sentence.	Redundant.
449.10(b)(8)	440.80.
449.10(b)(9)	440.90.
449.10(b)(10)	440.100.
449.10(b)(11)	440.110.
449.10(b)(12)	440.120.
449.10(b)(13)	440.130.
449.10(b)(14)	440.140.
449.10(b)(15)(i)(A) 1st sentence	440.150.
449.10(b)(15)(i)(A) last sentence	442.251(a), (c), 442.252.
449.10(b)(15)(i)(B)	440.150.
449.10(b)(15)(i)(C)	442.252.
449.10(b)(15)(i)(D)	Redundant.
449.10(b)(15)(i)(E)	440.150.
449.10(b)(15)(ii)	442.254.
449.10(b)(15)(iii)	440.150.
449.10(b)(15)(iv)	440.150.
449.10(b)(15)(v)	Redundant.
449.10(b)(15) undesignated paragraph after (v).	441.11.
449.10(b)(15)(vi)	442.30.
449.10(b)(16) introductory paragraph.	440.160.
449.10(b)(16)(i), (ii)	441.151.
449.10(b)(16)(iii) introductory paragraph.	441.152.
449.10(b)(16)(iii)(A) words before "and for whom".	Obsolete.
449.10(b)(16)(iii)(A) words after "of these regulations".	441.153.
449.10(b)(16)(iii)(B)	Obsolete.
449.10(b)(16)(iii)(C)–(E)	441.153.
449.10(b)(16)(iv)(A), except 2d sentence.	441.154.
449.10(b)(16)(iv)(A) 2d sentence	Redundant.
449.10(b)(16)(iv)(B)	441.155.
449.10(b)(16)(iv)(C)	441.156.
449.10(b)(17)	440.170.
449.10(c)(1) and (2)	441.13.
449.10(c)(3)	Surplusage.
449.10(c)(4)	441.40.
449.10(c)(5) except (ii)(A)–(G)	441.182.
449.10(c)(5)(ii)(A)–(G)	441.181.
449.10(d)(1)(i)	435.1009, 440.2.
449.10(d)(1)(ii), (iv)–(vi)	435.1009.
449.10(d)(1)(iii)	440.2.
449.10(d)(2)	440.270.
449.10(d)(3)	441.11.
449.12(a) introductory paragraph	442.300.
449.12(a)(1)	442.301.
449.12(a)(1)(i) 1st sentence	442.302.
449.12(a)(1)(i) 2d sentence	Unnecessary.
449.12(a)(1)(ii)(A)	442.305.
449.12(a)(1)(ii)(A)(*1*)(*i*)	442.306.
449.12(a)(1)(ii)(A)(*1*)(*ii*), (*iii*)	442.307.
449.12(a)(1)(ii)(A)(*2*)	442.308.
449.12(a)(1)(ii)(A)(*3*)	442.309.

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Old section	New section
449.12(a)(1)(ii)(A)(*4*)	442.310.
449.12(a)(1)(ii)(B)	442.311, 442.404.
449.12(a)(1)(ii)(C)	442.312, 442.405.
449.12(a)(1)(iii)	442.320, 442.406(d), (e).
449.12(a)(1)(iv), (v)	442.313.
449.12(a)(1)(vi)	442.314.
449.12(a)(1)(vii)	442.315, 442.415.
449.12(a)(2)	442.316, 442.425(a), (b).
449.12(a)(3)	442.317, 442.417, 442.476(c).
449.12(a)(4)(i)(A)–(E)	442.318(a)–(c), 442.319.
449.12(a)(4)(i)(F)	Obsolete.
449.12(a)(4)(ii), (iii)	442.318(d), (e).
449.12(a)(5) introductory paragraph.	442.321(a), 442.507(a).
449.12(a)(5)(i)	442.322, 442.508.
449.12(a)(5)(ii)	442.323(a), 442.509(a).
449.12(a)(5)(iii)	442.321(b), 442.507(b).
449.12(a)(5) undesignated paragraph following paragraph (iii).	442.323(b), 442.509(b).
449.12(a)(6)(i)	442.324(a), 442.325, 442.326(a), 442.446, 442.447(a)(1), (3), 442.448(a), (d).
449.12(a)(6)(ii)	442.327.
449.12(a)(6)(iii)	442.326(b), (c).
449.12(a)(6)(iv)	442.324(b).
449.12(a)(6)(v), (vi)	442.328.
449.12(a)(6)(vii), (viii)	442.329.
449.12(a)(6)(ix)	442.330, 442.511.
449.12(a)(7)(i)	442.331(a).
449.12(a)(7)(ii)–(iv)	442.332.
449.12(a)(7)(vi), (vii)	442.331(b).
449.12(a)(8)(i)	442.333.
449.12(a)(8)(ii)	442.334.
449.12(a)(8)(iii)	442.335.
449.12(a)(8)(iv)	442.337(b).
449.12(a)(8)(v)	442.336.
449.12(a)(8)(vi)	442.337(a).
449.12(a)(9) introductory paragraph.	442.338, 442.474(b).
449.12(a)(9)(i) and (A)–(C)	442.339, 442.481(a)–(e).
449.12(a)(9)(ii)	442.340, 442.481(f).
449.12(a)(9)(iii)	442.481(g).
449.12(a)(9)(iv)	442.341, 442.481(h).
449.12(a)(9)(v)	442.342, 442.478(a).
449.12(b) introductory paragraph	Unnecessary.
449.12(b)(1)	442.303.
449.12(b)(2)	442.304.
449.12(b)(3)	442.343.
449.12(b)(4)	442.344.
449.12(b)(5)	442.345.
449.12(b)(6)	442.346.
449.12(c) introductory paragraph	442.400.
449.12(c)(1)	442.418(a), (b).
449.12(c)(2)	442.410(a), (b).
449.12(c)(3) introductory paragraph, 1st sentence.	442.411.
449.12(c)(3) introductory paragraph, 2d sentence, and (i)–(ix).	442.401.
449.12(c)(4)–(6)	Obsolete.
449.13 introductory paragraph, 1st sentence, words before "the standards for".	Obsolete.
449.13 introductory paragraph, 1st sentence, words after "July 18, 1977".	442.400.
449.13 introductory paragraph 2d sentence.	Obsolete.

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Old section	New section
449.13(a)(1)(i)	442.402.
449.13(a)(1)(ii)	442.403.
449.13(a)(1)(iii)	442.406(a)–(c).
449.13(a)(1)(iv)	442.407.
449.13(a)(1)(v)	442.408.
449.13(a)(1)(vi)	442.409(a)(1), (2).
449.13(a)(1)(vii)	442.409(a)(3).
449.13(a)(1)(viii)	442.410(a)(2).
449.13(a)(1)(ix)	442.412.
449.13(a)(1)(x)	442.413.
449.13(a)(1)(xi)	442.414.
449.13(a)(2)(i) introductory paragraph, 1st sentence.	442.418(a).
449.13(a)(2)(i) introductory paragraph, 2d sentence, and (A) and (B).	442.420.
449.13(a)(2)(ii)	442.419.
449.13(a)(2)(iii)	442.418(a), (b)(1).
449.13(a)(2)(iv)	442.418(b)(2), (c).
449.13(a)(2)(v)	442.421.
449.13(a)(2)(vi)	442.422.
449.13(a)(2)(vii)	442.423.
449.13(a)(2)(viii)	442.424(c), 442.425(c).
449.13(a)(2)(ix)	442.424(a), (b).
449.13(a)(2)(x)	442.425(c).
449.13(a)(2)(xi), (xii)	442.426.
449.13(a)(3)(i)	Unnecessary.
449.13(a)(3)(ii)	442.427(b).
449.13(a)(3)(iii), (iv)	442.428.
449.13(a)(3)(v)	442.429.
449.13(a)(3)(vi)	442.427(a).
449.13(a)(3)(vii)	442.430.
449.13(a)(3)(viii)	442.431.
449.13(a)(3)(ix), (x)	442.432.
449.13(a)(3)(xi)	442.427(c).
449.13(b)(1)(i), (ii)	442.433.
449.13(b)(1)(iii)	442.434.
449.13(b)(1)(iv)–(vi)	442.435.
449.13(b)(1)(vii)	442.436.
449.13(b)(1)(viii)–(x)	442.437.
449.13(b)(1)(xi) introductory paragraph and (A)–(C).	442.438(a)–(e).
449.13(b)(1)(xi)(D) 1st sentence	442.439(a).
449.13(b)(1)(xi)(D) 2d sentence	442.438(f).
449.13(b)(1)(xi)(E)	442.439(b), (c).
449.13(b)(1)(xii)	442.440.
449.13(b)(1)(xiii)	442.441(b)–(d).
449.13(b)(2)	442.442.
449.13(b)(3)	442.443.
449.13(b)(4)	442.444.
449.13(b)(5)	442.445.
449.13(b)(6)(i)	442.447(a)(1), (2), (4), (5 (b), (c).
449.13(b)(6)(ii)	442.448.
449.13(b)(6)(iii), (iv)	442.449(a), (b).
449.13(b)(6)(v), (vi)	442.450(a)(2), (3).
449.13(b)(6)(vii), (viii)	442.451(a).
449.13(b)(6)(ix)	442.452.
449.13(b)(6)(x)	442.451(b).
449.13(b)(6)(xi)	442.450(a)(4), (b), (c).
449.13(b)(6)(xii)	442.453.
449.13(b)(6)(xiii)	442.449(c).
449.13(c)(1)	442.454.
449.13(c)(1)(i)	442.455.
449.13(c)(1)(ii)	442.456.
449.13(c)(2)(i)	442.457.
449.13(c)(2)(ii)	442.458.
449.13(c)(2)(iii)	442.459.
449.13(c)(2)(iv)	442.460.
449.13(c)(2)(v)	442.461.

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Old section	New section
449.13(c)(2)(vi)	442.462.
449.13(c)(3)(i)	442.401, 442.463(a).
449.13(c)(3)(ii)–(v)	442.463(b)–(e).
449.13(c)(3)(vi)	442.411(a), 442.464.
449.13(c)(4)(i)	442.465.
449.13(c)(4)(ii), (iii)	442.466(a)–(c).
449.13(c)(4)(iv) introductory paragraph, 1st sentence.	442.466(d).
449.13(c)(4)(iv) introductory paragraph, 2d sentence, and (A)–(C).	442.467(a).
449.13(c)(4)(v)	442.468.
449.13(c)(4)(vi)	442.467(b).
449.13(c)(4)(vii) 1st and 2d sentences.	442.469.
449.13(c)(4)(vii) 3d sentence	442.467(c).
449.13(c)(4)(vii) 4th and 5th sentences.	442.470.
449.13(c)(4)(viii), (ix)	442.471.
449.13(c)(4)(x), (xi)	442.472.
449.13(c)(4)(xii)–(xiv)	442.473.
449.13(c)(5)(i), (ii)	442.474(a), (c), (e).
449.13(c)(5)(iii), (iv)	442.475.
449.13(c)(5)(v)	442.477.
449.13(c)(5)(vi), (vii)	442.476.
449.13(c)(5)(viii)	442.474(d).
449.13(c)(6)(i), (ii)	442.478.
449.13(c)(6)(iii)	442.479
449.13(c)(6)(iv), (v)	442.480.
449.13(c)(7)(i) 1st sentence	442.483(a).
449.13(c)(7)(i) 2d sentence, (ii), (iii).	442.482.
449.13(c)(7)(iv)–(vi)	442.483(b)–(d).
449.13(c)(7)(vii)	442.484(a).
449.13(c)(7)(viii)	442.485.
449.13(c)(7)(ix)–(xi)	442.484(b)–(d).
449.13(c)(8)(i)–(iii)	442.486.
449.13(c)(8)(iv)	442.487.
449.13(c)(8)(v), (vi)	442.488.
449.13(c)(9)(i)	442.489(a).
449.13(c)(9)(ii)–(iv)	442.490(b)–(d).
449.13(c)(9)(v)	442.489(b).
449.13(c)(9)(vi)	442.490(a).
449.13(c)(10)(i)	442.491(a).
449.13(c)(10)(ii)	442.492.
449.13(c)(10)(iii), (iv)	442.493.
449.13(c)(10)(v), (vi)	442.491(b), (c).
449.13(c)(11)(i)	442.494.
449.13(c)(11)(ii)–(vi)	442.495.
449.13(c)(12)(i), (ii)	442.496.
449.13(c)(12)(iii), (iv)	442.497.
449.13(c)(12)(v), (vi)	442.498.
449.13(d)(1)(i)–(iii)	442.499.
449.13(d)(2)(i)	442.500.
449.13(d)(2)(ii), (iii)	442.501(a), (b).
449.13(d)(2)(iv)	442.424(c), 442.501(c).
449.13(d)(3)	442.502.
449.13(d)(4)	442.503.
449.13(d)(5)	442.504.
449.13(e)	442.416.
449.13(f)(1)(i)	442.505.
449.13(f)(1)(ii), (iii)	442.506.
449.13(f)(1)(iv)	442.511.
449.13(f)(1)(v)	442.510.
449.13(f)(2)	442.512.
449.13(g)(1)	442.513.
449.13(g)(2)	442.514.
449.13(g)(3)	442.515.
449.13(g)(4)	442.516.
449.13(h)(1)	442.401.
449.13(h)(2)	442.409(a)(4), 442.410(a)(1), (c).
449.13(h)(3)	Unnecessary.
449.13(h)(4)	442.409(a)(1), (2), (b).
449.13(h)(5)–(9)	442.401.
449.13(h)(10)	442.441(a).
449.20	431.51.
449.31	447.10.
449.32	447.25.
449.33(a) introductory paragraph	442.10, 442.100.
449.33(a)(1) introductory paragraph except words "(including hospitals)".	442.12(a), 442.101.
449.33(a)(1) introductory paragraph words "(including hospitals)".	Unnecessary.
449.33(a)(1)(i) words before "that the facility meets".	442.101(b).
449.33(a)(1)(i) words after "this chapter".	442.101(d), 442.200, 442.202, 442.253.
449.33(a)(1)(ii) words before "and in the case", except words "pursuant to section 1910 of the Act".	442.101(b)(2).
449.33(a)(1)(ii) words "pursuant to sec. 1910 of the Act".	442.1(a)(7).
449.33(a)(1)(ii) words after "title XVIII of the act".	442.202(c)(3).
449.33(a)(1)(iii) words before "except that", except words "pursuant to sec. 1905 of the Act".	442.101(b)(1), 442.200, 442.202(b), (c).
449.33(a)(1)(iii) words "pursuant to sec. 1905 of the Act".	442 1(a)(6).
449.33(a)(2) introductory paragraph except words "(including hospitals and skilled nursing facilities)".	442.12(a), 442.101(a), 442.250.
449.33(a)(2) introductory paragraph words "(including hospital and skilled nursing facilities)".	Unnecessary.
449.33(a)(2)(i) except words "in accordance with paragraph (a)(4)(iii) of this section" and paragraph (E).	442.112
449.33(a)(2)(i) words "in accordance with paragraph (a)(4)(iii) of this section".	Redundant.
449.33(a)(2)(i)(E)	Redundant.
449.33(a)(2)(ii) except words "in accordance with paragraph (a)(4)(iii)(A) of this section", and paragraphs (A)(*2*) and (*3*) and (D).	442.113.
449.33(a)(2)(ii) words "in accordance with paragraph (a)(4)(iii)(A) of this section".	Redundant.
449.33(a)(2)(ii)(A)(*2*)	Obsolete.
449.33(a)(2)(ii)(A)(*3*)	442.115.
449.33(a)(2)(ii)(D)	Redundant.
449.33(a)(3)	455.104.
449.33(a)(4)(i) and (ii) introductory paragraph.	442.100, 442.101(d).
449.33(a)(4)(ii)	442.105.
449.33(a)(4)(iii) except last sentence.	442.111.
449.33(a)(4)(iii) last sentence	442.110(a), 442.111(a).
449.33(a)(4)(iv)(A), (B)(*1*)	442.105(c), (d).
449.33(a)(4)(iv)(B)(*2*)	Obsolete.

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Old section	New section
449.33(a)(4)(v)	442.101(e).
449.33(a)(5)	431.610(h).
449.33(a)(6) 1st sentence	442.12(a).
449.33(a)(6) 2d sentence, words before "and the effective date".	442.15(a).
449.33(a)(6) 2d sentence, words after "of one year".	442.12(b).
449.33(a)(6) 3d sentence, words before "except that".	442.12(c), 442.15(b).
449.33(a)(6) 3d sentence, words after "by the survey agency" and before "or may elect".	442.15(b).
449.33(a)(6) 3d sentence, words after "period of certification".	442.12(d).
449.33(a)(6) 4th sentence	442.16.
449.33(a)(7), (8)	Surplusage.
449.33(a)(9)	442.20.
449.33(a)(10)	Redundant.
449.33(b)(1)	Redundant.
449.33(b)(2)	431.610(i).
449.40(a)(1) words before "and no reduction".	447.51.
449.40(a)(1) words after "under the plan".	447.53.
449.40(a)(2)	447.51.
449.40(a)(2)(i), (ii)	447.52.
449.40(a)(3) 1st and 2d sentences.	447.53.
449.40(a)(3)(i), (ii)	447.54.
449.40(a)(3)(iii)	447.55.
449.40(a)(3)(iv)	447.54.
449.40(a)(3)(v)	447.56.
449.40(a)(3)(vi) 1st sentence	447.57.
449.40(a)(3)(vi) 2d sentence.	447.58.
449.40(b)	447.59.
449.41	431.625.
449.70	433.36.
449.82(a)	431.501.
449.82(b)(1)–(7)	431.502.
449.82(b)(8)	431.521.
449.82(b)(9)–(11)	431.502.
449.82(c)(1)(i)–(ix)	431.503.
449.82(c)(1)(x)	431.504.
449.82(c)(2)	431.512.
449.82(c)(3)	431.510.
449.82(c)(4)	431.511.
449.82(c)(5) introductory paragraph words before "a State plan for".	431.523–431.526, 431.557–431.560.
449.82(c)(5) introductory paragraph words after "and (2) of this section" and (i).	431.527.
449.82(c)(5) introductory paragraph words after "and (2) of this section", and (i) 1st sentence.	431.566.
449.82(c)(5)(ii)	431.528, 431.569.
449.82(c)(5)(iii)	Redundant.
449.82(c)(5)(iv)	431.527, 431.568.
449.82(c)(5)(v) words before "which shall be".	431.529, 431.570.
449.82(c)(5)(v) words after "period of enrollment".	431.541, 431.581.
449.82(c)(5)(vi)	431.530, 431.571.
449.82(c)(5)(vii)	431.531, 431.572.
449.82(c)(5)(viii), (ix)	431.532, 431.573.
449.82(c)(5)(x)	431.533, 431.574.
449.82(c)(5)(xi)	431.534, 431.575.
449.82(c)(5)(xii)	431.535, 431.576.
449.82(c)(5)(xiii)	431.536, 431.577.
449.82(c)(5)(xiv)	431.537, 431.578.
449.82(c)(5)(xv)	431.565.
449.82(c)(5)(xvi)	431.522.
449.82(c)(6)(i)	431.540, 431.580.
449.82(c)(6)(ii)	431.541, 431.581.
449.83(c)(6)(iii)	431.542, 431.582.
449.82(c)(6)(iv)	431.543, 431.583.
449.82(c)(6)(v)	431.544, 431.584.
449.82(c)(6)(vi)	431.545, 431.585.
449.82(c)(6)(vii)	431.546, 431.586.
449.82(c)(6)(viii)	431.547.
449.82(c)(6)(ix)	431.548, 431.587.
449.82(c)(6)(x)	431.549, 431.588.
449.82(c)(6)(xi)	431.550, 431.589.
449.82(d)(1)	431.591.
449.82(d)(2)	431.592.
449.82(d)(3)	431.593.
449.82(d)(4)(i), (ii)	431.597.
449.82(d)(4)(iii)	431.594.
449.82(d)(4)(iv)	431.595.
449.82(d)(4)(v)	431.596.
449.100	Unnecessary.
449.101	441.201.
449.102	441.202.
449.103	441.203.
449.104	441.204.
449.105	441.205.
449.106	441.206.
449.107	441.207.
449.108	441.208.
449.109	Redundant with 45 CFR 205.50.

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Old section	New section
450.18 introductory paragraph	456.2.
450.18(a) introductory paragraph	456.3.
450.18(a)(1) introductory paragraph.	Unnecessary.
450.18(a)(1)(i)	456.22.
450.18(a)(1)(ii)	456.23.
450.18(a)(1)(iii)	456.3.
450.18(a)(1)(iv)	456.346, 456.347, 456.348.
450.18(a)(1)(v) except last sentence.	Unnecessary.
450.18(a)(1)(v) last sentence	456.171, 456.271, 456.372.
450.18(a)(2)	456.60, 456.160, 456.260, 456.360.
450.18(a)(3)(i) and (iii)	456.80.
450.18(a)(3)(ii)	456.80, 456.180, 456.280, 456.380.
450.18(a)(3)(iv)	456.280, 456.281.
450.18(a)(4)	456.3.
450.18(a)(5)	456.3.
450.18(b)	456.4.
450.18(c)	456.5.
450.18(d) words before "and will perform".	456.6.
450.18(d) words after "of this chapter".	Redundant.
450.18(e)	Redundant.
450.18(f)	Obsolete.

PART 450—Continued

Old section	New section
450.19(a) introductory paragraph first two words after caption and words after "intermediate care facility".	456.101.
450.19(a) first word, "mental Hospital," and words after "intermediate care facility" and before "which meets".	456.201(a).
450.19(a) first word and words after "mental hospital" except "and intermediate care".	456.301.
450.19(a) first word, words after "skilled nursing facility and" and 450.19(a)(4) introductory paragraph words after "Christian Science Sanatoriums.".	456.401.
450.19(a) introductory paragraph words after "* * * review plan * * *".	456.201(b).
450.19(a)(1) introductory paragraph.	456.102.
450.19(a)(1)(i)	456.113.
450.19(a)(1)(ii) introductory paragraph.	456.105.
450.19(a)(1)(ii)	456.106.
450.19(a)(1)(iii)(A)	456.129.
450.19(a)(1)(iii)(B)	456.142.
450.19(a)(1)(iii)(C)	456.129 and 456.134.
450.19(a)(1)(iv)	456.129 and 456.134.
450.19(a)(1)(v)	456.105.
450.19(a)(1)(vi)	456.112.
450.19(a)(1)(vii)	456.111.
450.19(a)(1)(viii) introductory paragraph words before "within one working day".	456.121.
450.19(a)(1)(viii) introductory paragraph words before "by the committee" except parenthetical note.	456.125.
450.19(a)(1)(viii) parenthetical note.	456.127.
450.19(a)(1)(viii) introductory paragraph words after "of such application".	456.123.
450.19(a)(1)(viii)(A)	456.126.
450.19(a)(1)(viii)(B) 1st and 2d sentences except words after "criteria and" and before "are applied".	456.122.
450.19(a)(1)(viii)(B) 1st and 2d sentences.	456.123.
450.19(a)(1)(viii)(B) 3d sentence	Obsolete.
450.19(a)(1)(viii)(C), (D), (E) words before "and written notification" and (F) words before "written notification thereof".	456.123.
450.19(a)(1)(viii)(E) words after "shall be considered final" and (F) words after "is not necessary.".	456.124.
450.19(a)(1)(ix)	456.128.
450.19(a)(1)(ix) words before "and recorded".	456.123.
450.19(a)(1)(ix) words after "shall be assigned" and before "based on the patient's".	456.111.
450.19(a)(1)(x) words before "by the Group".	456.135.
450.19(a)(1)(x) introductory paragraph.	456.135.
450.19(a)(1)(x)(A)	456.137.
450.19(a)(1)(x)(B)	456.135.
450.19(a)(1)(x)(C) 1st and 2d sentences except words after "criteria and" and before "are applied".	456.132.
450.19(a)(1)(x)(C) 1st and 2d sentences.	456.135.
450.19(a)(1)(x)(C) 3d sentence	Obsolete.
450.19(a)(1)(x)(D) words before "in accordance with".	456.135.
450.19(a)(1)(x)(D) words after "shall be determined".	456.133.
450.19(a)(1)(x)(E), (F), (G) words before "and written notification" and (H) words before "written notification".	456.135.
450.19(a)(1)(x)(G) words after "shall be considered final" and (H) words after "has not been justified".	456.136.
450.19(a)(1)(xi)(A) first 2 sentences.	456.141.
450.19(a)(1)(xi)(A) 3d and 4th sentences.	456.143.
450.19(a)(1)(xi)(A) 5th sentence	456.145.
450.19(a)(1)(xi)(A) 6th sentence	456.144.
450.19(a)(1)(xi)(B)	456.142.
450.19(a)(1)(xii)	456.142.
450.19(a)(2) introductory paragraph.	456.201(b).
450.19(a)(2)(i)	456.213.
450.19(a)(2)(ii) introductory paragraph.	456.205 (a) and (b).
450.19(a)(2)(ii)(A)	456.206(b).
450.19(a)(2)(ii)(B)	456.206(c).
450.19(a)(2)(iii)(A)	456.242(a).
450.19(a)(2)(iii)(B)	456.235(b).
450.19(a)(2)(iv)	456.235(a).
450.19(a)(2)(v)	456.205(c).
450.19(a)(2)(vi)	456.212.
450.19(a)(2)(vii)	456.211.
450.19(a)(2)(viii) words before "on or before a specified date".	456.231.
450.19(a)(2)(viii) words after "necessity of continued stay" and before 7th sentence.	456.233.
450.19(a)(2)(viii) 7th sentence	456.234(b).
450.19(a)(2)(viii) 8th sentence	456.211(e).
450.19(a)(2)(ix) introductory paragraph.	456.236(a).
450.19(a)(2)(ix)(A)	456.238.
450.19(a)(2)(ix)(B)	456.236(c).
450.19(a)(2)(ix)(C) 1st sentence	456.232(a), 456.236(c).
450.19(a)(2)(ix)(C) 2d sentence	456.232(b), 456.236(c).
450.19(a)(2)(ix)(C) 3d sentence	Obsolete.
450.19(a)(2)(ix)(D) words before "in accordance with".	456.236(d).
450.19(a)(2)(ix)(D) first sentence words after "is appropriate and".	456.211(e).
450.19(a)(2)(ix)(D) words after "date assigned".	456.234 (a) and (c).
450.19(a)(2)(ix)(D) second sentence words before "in like manner".	456.236(b).
450.19(a)(2)(ix)(E)	456.236(e).

PART 450—Continued

Old section	New section
450.19(a)(2)(ix)(F)	456.236(f).
450.19(a)(2)(ix)(G) words before "and written notification".	456.236(g).
450.19(a)(2)(ix)(G) words after "considered final".	456.237.
450.19(a)(2)(ix)(H) words before "written notification".	456.236(h).
450.19(a)(2)(ix)(H) words after "mental hospital services".	456.237.
450.19(a)(2)(x) introductory words.	456.242(b).
450.19(a)(2)(x)(A) 1st sentence	456.241(a).
450.19(a)(2)(x)(A) 2d sentence	456.241.
450.19(a)(2)(x)(A) 3d and 4th sentences.	456.243.
450.19(a)(2)(x)(A) 5th sentence	456.245.
450.19(a)(2)(x)(A) last sentence	456.244.
450.19(a)(2)(x)(B)	456.242(b).
450.19(a)(2)(xi)	456.242(b).
450.19(a)(3) introductory paragraph.	456.302.
450.19(a)(3)(i)	456.313.
450.19(a)(3)(ii) introductory paragraph.	456.305 (a) and (b).
450.19(a)(3)(ii)(A)	456.306(b).
450.19(a)(3)(ii)(B)	456.306(c).
450.19(a)(3)(iii)(A)	456.342(a).
450.19(a)(3)(iii)(B)	456.335
450.19(a)(3)(iv)	456.335.
450.19(a)(3)(v)	456.305(c).
450.19(a)(3)(vi)	456.312.
450.19(a)(3)(vii)	456.311.
450.19(a)(3)(viii) words before "on or before a specified date".	456.331.
450.19(a)(3)(viii) introductory paragraph.	456.333.
450.19(a)(3)(viii) introductory paragraph 2d sentence words before "is either".	456.311(e).
450.19(a)(3)(viii)(A) words before "but at least".	456.333.
450.19(a)(3)(viii)(A) words after "functional capabilities".	456.334(b).
450.19(a)(3)(viii)(B) words after "first 90 days".	456.334(b).
450.19(a)(3)(ix) introductory paragraph, (A) and (B) 1st and 2d sentences.	456.336 (a) and (c).
450.19(a)(3)(ix)(B) 2d sentence except words "and closer professional scrutiny".	456.332.
450.19(a)(3)(ix)(B) 3d and 4th sentence.	Obsolete.
450.19(a)(3)(ix)(C) words before "in accordance with".	456.336(d).
450.19(a)(3)(ix)(C) words after "date assigned".	456.334 (a) and (c).
450.19(a)(3)(ix)(C) after "is appropriate" and before "At the expiration".	456.311(e).
450.19(a)(3)(ix) last sentence words before "in like manner".	456.336(b).
450.19(a)(3)(ix)(D)	456.336(e).
450.19(a)(3)(ix)(E)	456.336(f).
450.19(a)(3)(ix)(F) words before "and written notification" and (G) words before "written notification".	456.336 (g) and (h).
450.19(a)(3)(ix)(F) words after "shall be considered final" and before "not later than" and words after "the assigned review date"; and (G) words after "nursing facility services" and before "not later than" and words after "assigned review date".	456.337.
450.19(a)(3)(ix)(F) words after "shall be sent" except (1)–(4) and (G) words after "shall be made" except (1)–(4).	456.388.
450.19(a)(3)(x)(A) 1st and 2d sentences.	456.341.
450.19(a)(3)(x)(A) 3d and 4th sentences.	456.343.
450.19(a)(3)(x)(A) 5th sentence	456.345.
450.19(a)(3)(x)(A) 6th sentence	456.344.
450.19(a)(3)(x)(B)	456.342(b).
450.19(a)(3)(xi)	456.342(b).
450.19(a)(4) introductory paragraph parenthetical note.	456.351.
450.19(a)(4) 2d and 3d sentences except (i)–(vii).	456.401.
450.19(a)(4)(i)	456.413.
450.19(a)(4)(ii) 1st sentence except "and by whom".	456.405.
450.19(a)(4)(ii)(A) words after "How, when and".	456.406.
450.19(a)(4)(ii)(B)	456.407.
450.19(a)(4)(iii)	456.435.
450.19(a)(4)(iv)	456.412.
450.19(a)(4)(v)	456.411.
450.19(a)(4)(vi) words before "or more frequently" and words after "at the time of assessment".	456.431.
450.19(a)(4)(vi) 1st sentence words after "for continued stay".	456.433, 456.434.
450.19(a)(4)(vii) introductory paragraph.	456.436.
450.19(a)(4)(vii)(A)	456.436.
450.19(a)(4)(vii)(B)	456.436.
450.19(a)(4)(vii)(B) 2d sentence except words "and closer professional scrutiny".	456.432.
450.19(a)(4)(vii)(C) words before "in accordance with".	456.436, 456.411(e).
450.19(a)(4)(vii)(C) words after "date assigned".	456.434.
450.19(a)(4)(vii)(C) 2d sentence words before "in like manner".	456.436.
450.19(a)(4)(vii)(D)	456.436.
450.19(a)(4)(vii)(E)	456.436.
450.19(a)(4)(vii)(F) words before "and written notification" and (G) words before "written notification".	456.436.
450.19(a)(4)(vii)(F) words after "snall be considered final" to words before "to: (1)" and (G) words after "intermediate care facility services" to words before "to: (1)".	456.438.

PART 450—Continued

Old section	New section
450.19(a)(4)(vii)(F) words after "shall be considered final" to words before "not later than" and words after "final determination"; and (G) words after "intermediate care facility services" and before "not later than" and words after "such final determination".	456.437.
450.19(b) 1st sentence	456.505.
450.19(b) 2d sentence	456.507.
450.19(b) 3d sentence	456.507.
450.19(b) 4th sentence	456.508
450.19(b) 5th sentence	Redundant.
450.19(b) 6th sentence	456.506.
450.19(b) 7th sentence	456.503.
450.19(b) 8th sentence	456.506.
450.19(c)(1)(i)	456.520.
450.19(c)(1)(ii)	Redundant.
450.19(c)(2)	456.521(a)(1).
450.19(c)(3)	456.522(i).
450.19(c)(4)	456.522(j).
450.19(c)(5) 1st sentence	456.521(a)(2).
450.19(c)(5) 2d sentence	456.523(a).
450.19(c)(6)	456.521(b).
450.19(c)(7)	456.522.
450.19(c)(7)(i)	456.522(a).
450.19(c)(7)(ii)	456.522(b).
450.19(c)(7)(iii)	456.522(c).
450.19(c)(7)(iv)	456.522(g).
450.19(c)(7)(v)	456.522(d).
450.19(c)(7)(vi)	456.522(e).
450.19(c)(7)(vii)	456.522(h).
450.19(c)(7)(viii)	456.522(f).
450.19(c)(7)(ix)	456.522(k).
450.19(c)(8) 1st sentence words before "upon receipt" and after "of this section,".	456.524(b).
450.19(c)(8) words after "agency shall," and before "promptly notify".	456.524(a)(1).
450.19(c)(8) 2d sentence	456.523(b).
450.19(c)(9) 1st sentence	456.524(a)(2).
450.19(c)(9) 2d sentence	456.525.
450.19(c)(9) 3d sentence	456.525.
450.20(a)	Redundant.
450.20(b)	Obsolete.
450.20(c) 1st sentence	456.501.
450.20(c) 2d, 3d, and 4th sentences.	456.506.
450.21	431.107.
450.23(a)	456.2.
450.23(a)(1) 1st and 2d sentences.	456.170, 456.180, 456.270, 456.280.
450.23(a)(1) 3d sentence	456.481, 456.482.
450.23(a)(1) 4th sentence	Redundant.
450.23(a)(1)(i)	456.170, 456.270.
450.23(a)(1)(ii)	456.180, 456.280.
450.23(a)(1)(iii)	456.281.
450.23(a)(1)(iv)	456.170, 456.181, 456.270.
450.23(a)(2)(i) and (ii)	456.602.
450.23(a)(2)(iii)	456.603.
450.23(a)(3)(ii)	456.604.
450.23(a)(3)(i)	456.605.
450.23(a)(3)(iii)	456.606, 456.607.
450.23(a)(3)(iv)	Redundant.
450.23(a)(3)(v) 1st and 2d sentences.	456.608.
450.23(a)(3)(v) 3d sentence	456.609.
450.23(a)(3)(v)(A)–(F)	456.610.
450.23(a)(4)(i)	456.611.
450.23(a)(4)(ii)	456.612.
450.23(a)(4)(iii)	456.613.
450.23(b)	456.614.
450.23(c)	Unnecessary.
450.24(a) Introductory paragraph except parenthetical note.	456.2.
450.24(a) Parenthetical note	456.601.
450.24(a)(1) Introductory paragraph.	456.370.
450.24(a)(1)(i)(A)–(C) 1st sentence.	456.370.
450.24(a)(1)(i)(C) 2d sentence	456.371.
450.24(a)(1)(ii)	456.380.
450.24(a)(1)(iii)	456.381.
450.24(a)(2)(i)	456.602.
450.24(a)(2)(ii)	456.603.
450.24(a)(3)(i)	456.605.
450.24(a)(3)(ii)	456.604.
450.24(a)(3)(iii)	456.606.
450.24(a)(3)(iv)	456.607.
450.24(a)(3)(v) 1st to 3d sentences.	456.608.
450.24(a)(3)(v) 4th santence	456.609.
450.24(a)(3)(v)(A)–(G)	456.610.
450.24(a)(4)(i)	456.611.
450.24(a)(4)(ii)	456.612.
450.24(a)(4)(iii)	456.613.
450.24(b)	Unnecessary.
450.24(c)	456.614.
450.30(a)(1)	447.201.
450.30(a)(2)(i), (ii)	447.261.
450.30(a)(2)(iii)	Redundant.
450.30(a)(3) introductory paragraph, words before "as determined".	447.273.
450.30(a)(3) introductory paragraph, words after "cost-related basis".	447.221.
450.30(a)(3)(i)(A)	447.275.
450.30(a)(3)(i)(B)	447.274.
450.30(a)(3)(i)(C)	447.276.
450.30(a)(3)(i)(D)	447.274.
450.30(a)(3)(i)(E)	447.277.
450.30(a)(3)(i)(F)	447.277.
450.30(a)(3)(ii) introductory paragraph, 1st sentence, words before "and shall describe".	Surplusage.
450.30(a)(3)(ii) introductory paragraph, 1st sentence words after "of this section".	447.290.
450.30(a)(3)(ii) introductory paragraph, 2d sentence.	447.294.
450.30(a)(3)(ii)(A)	447.294.
450.30(a)(3)(ii)(B)	447.291.
450.30(a)(3)(ii)(C)	Surplusage.
450.30(a)(3)(ii)(D)	447.292.
450.30(a)(3)(ii)(E) words before "which audits shall".	447.293.
450.30(a)(3)(ii)(E) words after "exceptional profiles".	Surplusage.
450.30(a)(3)(ii)(F)	447.295.
450.30(a)(3)(ii)(G)	447.296.
450.30(a)(3)(iii) introductory paragraph.	447.278.
450.30(a)(3)(iii)(A)	447.279.
450.30(a)(3)(iii)(B)	447.281.
450.30(a)(3)(iii)(C)	447.282, 447.283.
450.30(a)(3)(iii)(D)	447.284.

PART 450—Continued

Old section	New section
450.30(a)(3)(iv) introductory paragraph.	447.301.
450.30(a)(3)(iv)(A)	447.302.
450.30(a)(3)(iv)(B)	447.303.
450.30(a)(3)(iv)(C)	447.304.
450.30(a)(3)(iv)(D)	447.305.
450.30(a)(3)(iv)(E)	447.306.
450.30(a)(3)(iv)(F)	447.307.
450.30(a)(3)(v)	447.311.
450.30(a)(3)(vi)	447.272.
450.30(a)(4)	447.252.
450.30(a)(5)	447.202.
450.30(a)(6)	447.203.
450.30(a)(7)	447.204.
450.30(a)(8)	447.15.
450.30(a)(9)	Obsolete.
450.30(b) introductory paragraph, 1st sentence.	447.252.
450.30(b) introductory paragraph, 2d sentence.	Surplusage.
450.30(b) introductory paragraph, 3d sentence.	447.252.
450.30(b) introductory paragraph, last sentence.	447.40.
450.30(b)(1) words before "or, in the case of".	447.262.
450.30(b)(1) words after "for such services".	Redundant.
450.30(b)(2) introductory paragraph.	447.331.
450.30(b)(2)(i)	447.333.
450.30(b)(2)(ii)	447.332.
450.30(b)(2)(iii)	447.332.
450.30(b)(2)(iv) 1st sentence	447.334.
450.30(b)(2)(iv) 2d sentence	Redundant.
450.30(b)(3)(i), (ii)(A)	447.341.
450.30(b)(3)(ii)(B)	Obsolete.
450.30(b)(3)(ii)(C)	447.341.
450.30(b)(4)	447.351.
450.30(b)(5)	447.321, 447.322.
450.30(b)(6)(i)	447.316.
450.30(b)(6)(ii)	447.315.
450.30(b)(6)(iii)	447.315.
450.30(b)(7)	447.361.
450.30(c)	447.252.
450.30(d)(1)	447.252.
450.30(d)(2)	447.40.
450.31	433.135.
450.41	431.105.
450.70	431.115.
450.71	433.37.
450.80(a)(1)	455.11, 455.12, 455.13.
450.80(a)(2)	455.13.
450.80(a)(3)	455.13.
450.80(a)(4)	455.17.
450.80(a)(5)(i)	455.18.
450.80(a)(5)(ii)	455.19.
450.80(a)(5)(iii)	455.18.
450.80(a)(6)	455.20.
450.80(a)(7)	455.22.
450.80(a)(8)	455.21.
450.80(b)(1)	455.14.
450.80(b)(2)	455.15, 455.16.
450.80(c)	455.23.
450.80(d)	455.21.
450.90(a)	433.111.
450.90(b)(1)	433.112.
450.90(b)(2)	433.113.
450.90(b)(3)	433.114.
450.90(b)(4)	Unnecessary.

PART 450—Continued

Old section	New section
450.100 except (c), words "excluding * * * Massachusetts".	431.610.
450.100(c), words "excluding * * * Massachusetts".	442.12.
450.210	447.35.
450.220	447.30.

PART 451

Old section	New section
451.10	431.615.

PART 452

Old section	New section
452.10(a)	431.700.
452.10(b)(1)	431.701, 431.704.
452.10(b)(2)	431.701.
452.10(b)(3)	431.706.
452.10(b)(4)	431.701.
452.10(b)(5)	431.701.
452.10(b)(6)	431.710.
452.10(b)(7)	431.714.
452.10(c)	431.702.
452.10(c)(1)	431.703.
452.10(c)(2)	431.705.
452.10(c)(2)(i)	431.707.
452.10(c)(2)(ii)	431.708.
452.10(c)(2)(iii) 1st sentence	431.709.
452.10(c)(2)(iii) 2d and 3d sentences.	431.710.
452.10(c)(2)(iv)	431.711.
452.10(c)(2)(v)	431.712.
452.10(c)(2)(vi)	431.713.
452.10(d)	431.714.
452.10(e)	431.715.

NOTE: This list includes only new sections based on regulations existing before recodification. Sections containing new material that is introductory or explanatory have not been included.

PART 431

New section	Old section
431.12	446.10.
431.51	449.20.
431.52	448.40(a).
431.53	449.10(a)(5)(ii).
431.105	450.41.
431.107	450.21.
431.110	449.10(a)(11).
431.115	450.70.
431.501	449.82(a).
431.502	449.82(b)(1)–(7), (9)–(11).
431.503	449.82(c)(1)(i)–(ix).
431.504	449.82(c)(1)(x).
431.510	449.82(c)(3).
431.511	449.82(c)(4).

PART 431—Continued

New section	Old section
431.512	449.82(c)(2).
431.521	449.82(b)(8).
431.522	449.82(c)(5)(xvi).
431.523–431.526	449.82(c)(5) introductory paragraph words before "a State plan for".
431.527	449.82(c)(5) introductory paragraph words after "and (2) of this section" and (i), (iv).
431.528	449.82(c)(5)(ii).
431.529	449.82(c)(5)(v) words before "which shall be".
431.530	449.82(c)(5)(vi).
431.531	449.82(c)(5)(vii).
431.532	449.82(c)(5)(viii), (ix).
431.533	449.82(c)(5)(x).
431.534	449.82(c)(5)(xi).
431.535	449.82(c)(5)(xii).
431.536	449.82(c)(5)(xiii).
431.537	449.82(c)(5)(xiv).
431.540	449.82(c)(6)(i).
431.541	449.82(c)(5)(v) words after "period of enrollment" and (6)(ii).
431.542	449.82(c)(6)(iii).
431.543	449.82(c)(6)(iv).
431.544	449.82(c)(6)(v).
431.545	449.82(c)(6)(vi).
431.546	449.82(c)(6)(vii).
431.547	449.82(c)(6)(viii).
431.548	449.82(c)(6)(ix).
431.549	449.82(c)(6)(x).
431.550	449.82(c)(6)(xi).
431.557–431.560	449.82(c)(5) words before "a State plan for".
431.565	449.82(c)(5)(xv).
431.568	449.82(c)(5) introductory paragraph words after "and (2) of this section" and (i) 1st sentence, (iv).
431.569	449.82(c)(5)(ii).
431.570	449.82(c)(5)(v) words before "which shall be".
431.571	449.82(c)(5)(vi).
431.572	449.82(c)(5)(vii).
431.573	449.82(c)(5)(viii) and (ix).
431.574	449.82(c)(5)(x).
431.575	449.82(c)(5)(xi).
431.576	449.82(c)(5)(xii).
431.577	449.82(c)(5)(xiii).
431.578	449.82(c)(5)(xiv).
431.580	449.82(c)(6)(i).
431.581	449.82(c)(5)(v) words after "period of enrollment" and (6)(ii).
431.582	449.82(c)(6)(iii).
431.583	449.82(c)(6)(iv).
431.584	449.82(c)(6)(v).
431.585	449.82(c)(6)(vi).
431.586	449.82(c)(6)(vii).
431.587	449.82(c)(6)(ix).
431.588	449.82(c)(6)(x).
431.589	449.82(c)(6)(xi).
431.591	449.82(d)(1).
431.592	449.82(d)(2).

PART 431—Continued

New section	Old section
431.593	449.82(d)(3).
431.594	449.82(d)(4)(iii).
431.595	449.82(d)(4)(iv).
431.596	449.82(d)(4)(v).
431.597	449.82(d)(4)(i), (ii).
431.610	450.100
431.615	45 .10.
431.625	449.41.
431.700	452.10(a).
431.701	452.10(b)(1), (2), (4), (5).
431.702	452.10(c).
431.703	452.10(c)(1).
431.704	452.10(b)(1).
431.705	452.10(c)(2).
431.706	452.10(b)(3).
431.707	452.10(c)(2)(i).
431.708	452.10(c)(2)(ii).
431.709	452.10(c)(2)(iii) 1st sentence.
431.710	452.10(b)(6) and 452.10(c)(2)(iii) 2d and 3d sentences.
431.711	452.10(c)(2)(iv).
431.712	452.10(c)(2)(v).
431.713	452.10(c)(2)(vi).
431.714	452.10(b)(7) and 452.10(d).
431.715	452.10(e).

PART 432

New section	Old section
432.2	446.151.
432.10	446.160.
432.30	446.170.
432.31	446.165.
432.32	446.168.
432.50	446.175.
432.55	446.180
432.60	446.185.

PART 433

New section	Old section
433.36	449.70.
433.37	450.71.
433.111	450.90(a).
433.112	450.90(b)(1).
433.113	450.90(b)(2).
433.114	450.90(b)(3).
433.135	450.31.

PART 435

New section	Old section
435.2	"Note" at beginning of 448.1.

PART 435—Continued

New section	Old section
435.10	448.1(b) 1st sentence. 448.1(c) 1st sentence. 448.1(e). 448.3(a)(1)(ii)(c), 1st sentence.
435.110	448.1(b)(1)(i). 448.10(b)(1)(i).
435.111	448.1(b)(1)(ii).
435.112	448.1(b)(1)(iii).
435.113	448.1(b)(3)(i).
435.114	448.1(b)(3)(ii).
435.120	448.1(b)(2)(i).
435.121	448.1(b)(2)(iii).
435.122	448.1(b)(3)(i).
435.130	448.1(b)(2)(iv).
435.131	448.1(b)(2)(v).
435.132	448.1(b)(2)(vi).
435.133	448.1(b)(2)(vii).
435.134	448.1(b)(3)(ii).
435.135	448.1(b)(2)(viii).
435.200	448.1(c) 1st sentence.
435.210	448.1(c)(1).
435.211	448.1(c)(2).
435.220	448.1(c)(6).
435.221	448.1(c)(5).
435.222	448.1(c)(4).
435.223(a)	448.1(c)(3).
435.230	448.1(b)(2)(ii). 448.2(d).
435.231	448.2(e).
435.301	448.1(a)(2)(i). 448.1(d)(1).
435.310	448.1(d)(1).
435.320	448.1(d)(1).
435.321	448.1(a)(1)(ii)(A) and (d)(1).
435.325	445.1(d)(2).
435.401	448.2(a) and (c).
435.402	448.50.
435.403	448.40(b).
435.404	448.3(b)(6).
435.510	448.1(c) and 448.2(b)(1)
435.520	448.30(a), (b)(2), (3).
435.530	448.70(a)(1).
435.531	448.70(a)(2), (3), (b), (c)(1).
435.540	448.80(a)(1).
435.541	448.80(a)(2), (b), (c)(1).
435.602	448.3(b)(1)(iii).
435.603	448.3(b)(1)(ii)
435.711	448.3(a)(1)(i).
435.712	448.3(b)(1)(i), (5)(i)–(iii).
435.721	448.2(e), 448.3(a)(1)(ii)(A) and (B), (b)(2)(iii).
435.722	448.2(e).
435.723	448.3(b)(1)(i), (2).
435.724	448.3(b)(1)(i), (3).
435.725	448.3(b)(7), (8).
435.731	448.3(b)(7), (b)(9).
435.732	448.1(a)(1)(ii), (b)(2)(iii), 448.3(b)(8), (9).
435.733	448.3(b)(8).
435.734	448.3(b)(4).
435.740	448.1(a)(3).
435.811	448.3(b)(2)(iv), (3)(v), (5)(v), (c)(1)(i). 448.4(b)(4)(ii).
435.812	448.3(c)(1)(ii)(B), (iii).
435.813	448.3(b)(7).
435.814	448.3(b)(2)(iv), (3)(v), (5)(iv), (c)(1)(ii)(B), (iii).
435.815	448.3(b)(2)(iv), (7).
435.816	448.3(b)(3)(v), (5)(iv)(c)(1)(ii)(A), 448.4(b)(4)(ii)(B).
435.821	448.3(b)(5).
435.822	448.3(b)(2), (3).
435.823	448.3(b)(4).
435.831	448.1(a)(2)(ii), (b)(2)(iv), (3)(v), (5)(iv), (c)(2), (3), (4).
435.832	448.3(b)(7), (8).
435.840	448.3(c)(1)(iv).
435.841	448.3(c)(1)(iv).
435.845	448.3(c)(3), (4).
435.1001	448.4(a), 448.70(c)(2), and 448.80(c)(2).
435.1002	448.4(b)(1), (5), (8).
435.1003	448.4(b)(7).
435.1004	448.4(b)(6).
435.1005	448.4(b)(3), (c).
435.1006	448.3(a)(1)(ii)(B)(2) 448.4(b)(3), (c).
435.1007	448.4(b)(4), (c).
435.1008	448.4(b)(2), 448.60(a)(1)-(3)(i), (iv).
435.1009	448.60(a)(3)(ii), (iii)(b)(1)-(11), 449.10(d)(1).
435.1010	448.4(d).
435.1011	448.4(e).

PART 436

New section	Old section
436.10	448.10(b), 448.21(a).
436.110	448.10(b)(1)(i).
436.111	448.10(b)(1)(iii).
436.112	448.10(b)(3).
436.115	448.10(b)(1)(ii).
436.116(a)	448.10(b)(4).
436.210	448.10(b)(2)(i).
436.211	448.10(b)(2)(ii).
436.212	448.10(b)(2)(iii).
436.220	448.10(b)(2)(vi).
436.221	448.10(b)(2)(v).
436.222	448.10(b)(2)(iv).
436.230	448.11.
436.301	448.10(b)(5) 1st sentence.
436.310	448.10(b)(5) 1st sentence.
436.320	448.10(b)(5) 1st sentence.
436.330	448.10(b)(5) 1st sentence.
436.401	448.10(c)(1), (3)(4).
436.402	448.50.
436.403	448.40.
436.404	448.21(a)(2)(vi).
436.510	448.10(c)(3).
436.520	448.30.
436.530	448.70.
436.531	448.70.
436.540	448.80.
436.541	448.80.
436.602	448.21(a)(2)(ii).

PART 436—Continued

New section	Old section
436.603	448.21(a)(2)(i)(c) 1st sentence words after "applicant or recipient" and 2d sentence.
436.711	448.21(a)(1)(i), (a)(2)(iv), (v).
436.811	448.21(a)(3)(i)(A).
436.812	448.21(a)(3)(i)(B); 448.21(a)(2)(v).
436.813	448.21(a)(3)(1)(C).
436.821	448.21(a)(2)(iv), (v).
436.831	448.21(a)(3)(ii), (iii), (iv).
436.832	448.21(a)(3)(i)(C) except 1st and 2d sentence.
436.840	448.21(a)(3)(i)(D).
436.845	448.21(a)(3)(iii), (iv).
436.1001	448.10(d).
436.1002(a)	448.10(d)(1).
436.1002(b)	448.10(d)(3).
436.1003	448.10(d)(4).
436.1004(a)	448.10(d)(2) paragraph after (vi).
436.1004(b)	448.60(a)(3)(i).
436.1004(c)	448.60(a)(3)(iv).
436.1005	448.60.

PART 440

New section	Old section
440.2	449.10(b) introductory paragraph; 449.10(d)(1).
440.10	449.10(b)(1).
440.20	449.10(b)(2).
440.30	449.10(b)(3).
440.40	449.10(b)(4)(i)(A), (C), (ii) 1st sentence.
440.50	449.10(b)(5).
440.60	449.10(b)(6).
440.70	449.10(b)(7).
440.80	449.10(b)(8).
440.90	449.10(b)(9).
440.100	449.10(b)(10).
440.110	449.10(b)(11).
440.120	449.10(b)(12).
440.130	449.10(b)(13).
440.140	449.10(b)(14).
440.150	449.10(b)(15)(i)(A) 1st sentence, (B), (iii).
440.160	449.10(b)(16) introductory paragraph.
440.170	449.10(b)(17).
440.210	449.10(a)(1).
440.220	449.10(a)(2).
440.230	449.10(a)(5)(i).
440.240	449.10(a)(6) introductory paragraph and (7).
440.250	449.10(a)(6)(i)–(vii).
440.260	449.10(a)(8).

PART 441

New section	Old section
441.11	449.10(d)(3).
441.13	449.10(c)(1), (2).
441.15	449.10(a)(4).
441.20	449.10(a)(9).
441.30	449.10(a)(10).
441.40	449.10(c)(4).
441.51	449.10(a)(3) introductory paragraph.
441.52	449.10(b)(4)(ii) 2d and 3d sentences.
441.53	449.10(a)(3)(iv).
441.54	449.10(a)(3)(i).
441.55	449.10(a)(3)(ii).
441.56	449.10(a)(3)(iii).
441.151	449.10(b)(16)(i), (ii).
441.152	449.10(b)(16)(iii) introductory paragraph.
441.153	449.10(b)(16)(iii)(A) words after "of these regulations", and (C)-(E).
441.154	449.10(b)(16)(iii)(A) words before "and for whom".
441.155	449.10(b)(16)(iv)(B).
441.156	449.10(b)(16)(iv)(C).
441.181	449.10(c)(5)(ii)(A)–(G).
441.182	449.10(c)(5)(i) and (ii) introductory paragraph.
441.201	449.101.
441.202	449.102.
441.203	449.103.
441.204	449.104.
441.205	449.105.
441.206	449.106.
441.207	449.107.
441.208	449.108.

PART 442

New section	Old section
442.1	449.33(a)(1)(ii) words "pursuant to section 1910 of the Act" and (iii) words "pursuant to section 1905 of the Act".
442.10	449.33(a) introductory paragraph.
442.12	449.33(a)(1) except words "(including hospitals)," (6) 2d sentence, words after "of one year", 3d sentence, words before "except that" and after "period of certification" 450.100(c).
442.15	449.33(a)(6) 2d sentence words before "and the effective date" 3d sentence, words before "or may elect".
442.16	449.33(a)(6) 4th sentence.
442.20	449.33(a)(9).
442.30	449.10(b)(4)(i)(C).

PART 442—Continued

New section	Old section
442.100	449.33(a)(4)(i) and (ii) introductory paragraph.
442.101	449.33(a)(1) introductory paragraph except words "(including hospitals)," (i), (ii) words before "and in the case" except words "pursuant to section 1910 of the Act", (iii) words before "and in the case" except words "Pursuant to section 1905 of the Act", (2) introductory, paragraph except words "(including hospitals and skilled nursing facilities)", (4)(i), (ii) introductory paragraph, (v).
442.105	449.33(a)(4)(ii), (iv)(A), (B)(*1*).
442.110	449.33(a)(4)(iii) last sentence.
442.111	449.33(a)(4)(iii) last sentence.
442.112	449.33(a)(2)(i) except words "in accordance with paragraph (a)(4)(iii) of this section".
442.113	449.33(a)(2)(ii) except words "in accordance with paragraph (a)(4)(iii)(A) of this section", and paragraphs (A)(*2*) and (*3*) and (D).
442.115	449.33(a)(2)(ii) (A)(*3*).
442.200	449.33(a)(1)(iii) words before "except that" except words "pursuant to section 1905 of the Act".
442.201	449.10(a)(11), (b)(4)(i)(B).
442.202	449.33(a)(1)(i) words after "this chapter", (ii) words after "title XVIII of the Act," (iii) words before "except that" except words "pursuant to section 1905 of the Act".
442.250	449.33(a)(2) introductory paragraph except words "(including hospitals and skilled nursing facilities)".
442.251	449.10(a)(11)(b) (15)(i)(A)
442.252	449.10(b)(15)(i) (C).
442.253	449.33(a)(1)(i) words after "this chapter".
442.254	449.10(b)(15)(ii).
442.300	449.12(a) introductory paragraph.
442.301	449.12(a)(1).
442.302	449.12(a)(1)(i) 1st sentence.
442.303	449.12(b)(1)
442.304	449.12(b)(2).
442.305	449.12(a)(1)(ii) (A).
442.306	449.12(a)(1)(ii) (A)(*1*)(*i*).
442.307	449.12(a)(1)(ii) (A)(*1*)(*ii*), (*iii*).
442.308	449.12(a)(1)(ii) (A)(*2*).
442.309	449.12(a)(1)(ii) (A)(*3*).
442.310	449.12(a)(ii)(A) (*4*).
442.311	449.12(a)(1)(ii) (B)
442.312	449.12(a)(1)(ii) (C).
442.313	449.12(a)(1)(iv), (v)
442.314	449.12(a)(1)(vi).
442.315	449.12(a)(1)(vii).
442.316	449.12(a)(2).
442.317	449.12(a)(3).
442.318	449.12(a)(4)(i)(A)–(E), (ii), (iii).
442.319	449.12(a)(4)(i)(C).
442.320	449.12(a)(1)(iii).
442.321	449.12(a)(5) introductory paragraph, (iii).
442.322	449.12(a)(5)(i).
442.323	449.12(a)(5)(ii), undesignated paragraph following paragraph (iii).
442.324	449.12(a)(6)(i) 1st sentence, (iv)
442.325	449.12(a)(6)(i) 2d and 3d sentences and paragraph (ii).
442.326	449.12(a)(6)(i) 2d sentence, (iii).
442.327	449.12(a)(6)(ii).
442.328	449.12(a)(6)(v), (vi)
442.329	449.12(a)(6)(vii), (viii)
442.330	449.12(a)(6)(ix)
442.331	449.12(a)(7)(i), (vi), (vii)
442.332	449.12(a)(7)(ii)–(iv).
442.333	449.12(a)(8)(i).
442.334	449.12(a)(8)(ii)
442.335	449.12(a)(8)(iii)
442.336	449.12(a)(8)(v).
442.337	449.12(a)(8)(iv), (vi).
442.338	449.12(a)(9) introductory paragraph.
442.339	449.12(a)(9)(i) introductory paragraph and (A)–(C).
442.340	449.12(a)(9)(ii)
442.341	449.12(a)(9)(iv)
442.342	449.12(a)(9)(v)
442.343	449.12(b)(3)
442.344	449.12(b)(4).
442.345	449.12(b)(5).
442.346	449.12(b)(6).
442.400	449.13 introductory paragraph, 1st sentence, words after "July 18, 1977".
442.401	449.12(c)(3) introductory paragraph, 2d sentence, and paragraphs (i)–(ix), 449.13(c)(3)(i), (h)(1), (5)–(9).
442.402	449.13(a)(1)(i).
442.403	449.13(a)(1)(ii).
442.404	449.12(a)(1)(ii)(B).
442.405	449.12(a)(1)(ii)(C).

PART 442—Continued

New section	Old section
442.406	449.12(a)(1)(iii), 449.13(a)(1)(iii).
442.407	449.13(a)(1)(iv).
442.408	449.13(a)(1)(v).
442.409	449.13(a)(1)(vi), (vii)(h)(2), (4).
442.410	449.13(c)(2), 449.13(a)(1)(viii), (h)(2).
442.411	449.12(c)(3) introductory paragraph, 1st sentence, 449.13(c)(3)(vi).
442.412	449.13(a)(1)(ix).
442.413	449.13(a)(1)(x).
442.414	449.13(a)(1)(xi).
442.415	449.12(a)(1)(vii).
442.416	449.13(e).
442.417	449.12(a)(3)(i).
442.418	449.12(c)(1), 449.13(a)(2)(i) introductory paragraph, 1st sentence (iii), (iv).
442.419	449.13(a)(2)(ii).
442.420	449.13(a)(2)(i) introductory paragraph, 2d sentence, and (A), (B)
	442.421
	449.13(a)(2)(v).
442.422	449.13(a)(2)(vi).
442.423	449.13(a)(2)(vii).
442.424	449.13(a)(2)(viii), (ix), (d)(2)(iv).
442.425	449.12(a)(2), 449.13(a)(viii), (x).
442.426	449.13(a)(2)(xi), (xii).
442.427	449.13(a)(3)(ii), (vi), (xi).
442.428	449.13(a)(3)(iii), (iv).
442.429	449.13(a)(3)(v).
442.430	449.13(a)(3)(vii).
442.431	449.13(a)(3)(viii).
442.432	449.13(a)(3)(ix), (x).
442.433	449.13(b)(1)(i), (ii).
442.434	449.13(b)(1)(iii).
442.435	449.13(b)(1)(iv)–(vi).
442.436	449.13(b)(1)(vii).
442.437	449.13(b)(1)(viii)–(x).
442.438	449.13(b)(1)(xi) introductory paragraph, (A)–(C), (D) 2d sentence.
442.439	449.13(b)(1)(xi)(D) 1st sentence, (E).
442.440	449.13(b)(1)(xii).
442.441	449.13(b)(1)(xiii), (h)(10).
442.442	449.13(b)(2).
442.443	449.13(b)(3).
442.444	449.13(b)(4).
442.445	449.13(b)(5).
442.446	449.12(a)(6)(i).
442.447	449.12(a)(6)(i), 449.13(b)(6)(i).
442.448	449.12(a)(6)(i), 449.13(b)(6)(ii).
442.449	449.13(b)(6)(iii), (iv), (xiii).
442.450	449.13(b)(6)(v), (vi), (xi).
442.451	449.13(b)(6)(vii), (viii), (x).
442.452	449.13(b)(6)(ix).
442.453	449.13(b)(6)(xii).
442.454	449.13(c)(1).
442.455	449.13(c)(1)(i).
442.456	449.13(c)(1)(ii).
442.457	449.13(c)(2)(i).
442.458	449.13(c)(2)(ii).
442.459	449.13(c)(2)(iii).
442.460	449.13(c)(2)(iv).
442.461	449.13(c)(2)(v).
442.462	449.13(c)(2)(vi).
442.463	449.13(c)(3)(i)–(v).
442.464	449.13(c)(3)(vi).
442.465	449.13(c)(4)(i).
442.466	449.13(c)(4)(ii), (iii), (iv) introductory paragraph, 1st sentence.
442.467	449.13(c)(4)(iv) introductory paragraph, 2d sentence, (A)–(C), (vi), (vii) 3d sentence.
442.468	449.13(c)(4)(v).
442.469	449.13(c)(4)(vii) 1st and 2d sentences.
442.470	449.13(c)(4)(vii) 4th and 5th sentences.
442.471	449.13(c)(4)(viii), (ix).
442.472	449.13(c)(4)(x), (xi).
442.473	449.13(c)(4)(xii)–(xiv).
442.474	449.12(a)(9) introductory paragraph, 449.13(c)(5)(i), (ii), (viii).
442.475	449.13(c)(5)(iii), (iv).
442.476	449.12(a)(3)(ii), 449.13(c)(5)(vi), (vii).
442.477	449.13(c)(5)(v).
442.478	449.12(a)(9)(v) words before "and, in the case of," 449.13(c)(6)(i), (ii).
442.479	449.13(c)(6)(iii).
442.480	449.13(c)(6)(iv), (v).
442.481	449.12(a)(9)(i)–(iv).
442.482	449.13(c)(7)(i) 2d sentence, (ii), (iii).
442.483	449.13(c)(7)(i) 1st sentence, (iv)–(vi).
442.484	449.13(c)(7)(vii), (ix)–(xi).
442.485	449.13(c)(7)(viii).
442.486	449.13(c)(8)(i)–(iii).
442.487	449.13(c)(8)(iv).
442.488	449.13(c)(8)(v), (vi).
442.489	449.13(c)(9)(i), (v).
442.490	449.13(c)(9)(ii)–(iv), (vi).
442.491	449.13(c)(10)(i), (v), (vi).
442.492	449.13(c)(10)(ii).
442.493	449.13(c)(10)(iii), (iv).
442.494	449.13(c)(11)(i).
442.495	449.13(c)(11)(ii)–(vi).
442.496	449.13(c)(12)(i), (ii).
442.497	449.13(c)(12)(iii), (iv).
442.498	449.13(c)(12)(v), (vi).
442.499	449.13(d)(1)(i)–(iii).
442.500	449.13(d)(2)(i).
442.501	449.13(d)(2)(ii)–(iv).
442.502	449.13(d)(3).
442.503	449.13(d)(4).
442.504	449.13(d)(5).
442.505	449.13(f)(1)(i).
442.506	449.13(f)(1)(ii), (iii).
442.507	449.12(a)(5) introductory paragraph, (iii).
442.508	449.12(a)(5)(i).

PART 442—Continued

New section	Old section
442.509	449.12(a)(5)(ii), undesignated paragraph following paragraph (iii).
442.510	449.13(f)(1)(v).
442.511	449.12(a)(6)(ix), 449.13(f)(1)(iv).
442.512	449.13(f)(2).
442.513	449.13(g)(1).
442.514	449.13(g)(2).
442.515	449.13(g)(3).
442.516	449.13(g)(4).

PART 447

New section	Old section
447.10	449.31.
447.15	450.30(a)(8)
447.25	449.32.
447.30	450.220.
447.35	450.210.
447.40	450.30(b) introductory paragraph, last sentence, and (d)(1).
447.51	449.40(a)(1) words before "and no deduction" and (2) introductory paragraph.
447.52	449.40(a)(2)(i), (ii).
447.53	449.40(a)(1) words after "under the plan" and (3) introductory paragraph.
447.54	449.40(a)(3) (i), (ii), (iv).
447.55	449.40(a)(3)(iii).
447.56	449.40(a)(3)(v).
447.57	449.40(a)(3)(vi) 1st sentence.
447.58	449.40(a)(3)(vi) 2d sentence.
447.59	449.40(b).
447.201	450.30(a)(1).
447.202	450.30(a)(5).
447.203	450.30(a)(6).
447.204	450.30(a)(7).
447.251	450.30(a)(3) introductory paragraph, words after "cost-related basis."
447.252	450.30(b) introductory paragraph, except 2d and last sentences, (C), (d)(1).
447.261	450.30(a)(2) except (iii).
447.262	450.30(b)(1) except words after "for such services".
447.272	450.30(a)(3)(vi).
447.273	450.30(a)(3) introductory paragraph, words before "as determined".
447.274	450.30(a)(3)(i)(B), (D).
447.275	450.30(a)(3)(i)(A).
447.276	450.30(a)(3)(i)(C).
447.277	450.30(a)(3)(i)(E), (F).
447.279	450.30(a)(3)(iii)(A).
447.281	450.30(a)(3)(iii)(B).

PART 447—Continued

New section	Old section
447.282	450.30(a)(3)(iii)(C).
447.283	450.30(a)(3)(iii)(C)
447.284	450.30(a)(3)(iii)(D).
447.290	450.30(a)(3)(ii) introductory paragraph, works after "of this section".
447.291	450.30(a)(3)(ii)(B).
447.292	450.30(a)(3)(ii)(D).
447.293	450.30(a)(3)(ii)(E) except words after "exceptional profiles".
447.294	450.30(a)(3)(ii) introductory paragraph, 2d sentence and (A).
447.295	450.30(a)(3)(ii)(F).
447.296	450.30(a)(3)(ii)(G).
447.302	450.30(a)(3)(iv)(A).
447.303	450.30(a)(3)(iv)(B).
447.304	450.30(a)(3)(iv)(C).
447.305	450.30(a)(3)(iv)(D).
447.306	450.30(a)(3)(iv)(E).
447.307	450.30(a)(3)(iv)(F).
447.311	450.30(a)(3)(v).
447.315	450.30(b)(6) (ii), (iii).
447.316	450.30(b)(6)(i).
447.321	450.30(b)(5).
447.322	450.30(b)(5).
447.341	450.30(b)(3) except (ii)(B).
447.351	450.30(b)(4).

PART 455

New section	Old section
455.11	450.80(a)(1) last sentence.
455.12	450.80(a)(1) 1st sentence.
455.13	450.80(a)(1) 1st sentence, (2), (3).
455.14	450.80(b)(1).
455.15, 455.16	450.80(b)(2).
455.17	450.80(a)(4).
455.18	450.80(a)(5)(i), (iii).
455.19	450.80(a)(5)(ii), (6).
455.20	450.80(a)(6).
455.21	450.80(d).
455.22	450.80(a)(7).
455.23	450.80(c).
455.104	449.33(a)(3).
455.300	450.310.

PART 456—UTILIZATION CONTROL

New section	Old section
456.2	450.18 introductory paragraph, 450.23(a), 450.24(a) introductory paragraph except parenthetical note.
456.3	450.18(a), (iii), (4), (5).
456.4	450.18(b).
456.5	450.18(c).

PART 456—UTILIZATION CONTROL—Continued

New section	Old section
456.6	450.18(d) words before "and will perform."
456.22	450.18(a)(1)(i).
456.23	450.18(a)(1)(ii).
456.60	450.18(a)(2).
456.80	450.18(a)(3)(i) and (iii).
456.101	450.19(a) first two words and words after "intermediate care facility."
456.102	450.19(a)(1) introductory paragraph.
456.105	450.19(a)(1)(ii) introductory paragraph and (v).
456.106(b) and (c)	450.19(a)(1)(ii).
456.111	450.19(a)(1)(vii) and (ix) words after "admission is necessary" and before "based on the patient's."
456.112	450.19(a)(1)(vi).
456.113	450.19(a)(1)(i).
456.121	450.19(a)(1)(viii) introductory paragraph words before "within one working day."
456.122	450.19(a)(1)(viii)(B), 1st and 2d sentences except words after "criteria and" and before "are applied."
456.123	450.19(a)(1)(viii) introductory paragraph words after "of such application", (B) 1st and 2d sentences, (C), (D), (E) words before "and written notification", (F) words before "written notification thereof", and (ix) words before "is recorded."
456.124	450.19(a)(1)(viii)(E) words after "shall be considered final" and (F) words after "is not necessary."
456.125	450.19(a)(1)(viii) introductory paragraph words before "by the committee" except parenthetical notes.
456.126	450.19(a)(1)(viii)(A).
456.127	450.19(a)(1)(viii) parenthetical note.
456.128	450.19(a)(1)(ix).
456.129	450.19(a)(1)(iii) (A) and (C), and (iv).
456.132	450.19(a)(1)(x)(C) 1st and 2d sentences except words after "criteria and" and before "are applied."
456.133	450.19(a)(1)(x)(D) words after "shall be determined."
456.134	450.19(a)(1) (iii)(C) and (iv).
456.135	450.19(a)(1)(x) (B), (C) words before "The single State agency", (D), (E), (F), (G) words before "and written notification", and (H) words before "written notification."
456.136	450.19(a)(1)(x)(G) words after "shall be considered final" and (H) words after "has not been justified."
456.137	450.19(a)(1)(x)(A).
456.141	450.19(a)(1)(xi).
456.142	450.19(a)(1)(iii)(B), (xi)(B), and (xii).
456.143	450.19(a)(1)(xi)(A) 3d and 4th sentences.
456.144	450.19(a)(1)(xi)(A) 6th sentence.
456.145	450.19(a)(1)(xi)(A) 5th sentence.
456.160	450.18(a)(2).
456.170	450.23(a)(1) introductory paragraph 1st and 2d sentences, (i) and (iv).
456.171	450.18(a)(1)(v) last sentence.
456.180	450.13(a)(3)(ii), 450.23(a)(1) introductory paragraph 1st and 2d sentences, (ii), and (iv).
456.201(a)	450.19(a) introductory paragraph 1st word, "mental hospital", words after "review plan" and (2) introductory paragraph.
456.205	450.19(a)(2)(ii) introductory paragraph and (v).
456.206(b) and (c)	450.19(a)(2)(ii).
456.211	450.19(a)(2)(vii), (viii) last sentence and (ix)(D) 1st sentence words after "is appropriate and."
456.212	450.19(a)(2)(vi).
456.213	450.19(a)(2)(i).
456.231	450.19(a)(2)(viii) words before "on or before a specified date."
456.232	450.19(a)(2)(ix)(C) 1st sentence.
456.233	450.19(a)(2)(viii) words after "necessity of continued stay" and before "Subsequent reviews"; and last sentence.
456.234	450.19(a)(2)(viii) words after "30 days after admission," and before "The assigned review date", and (ix)(D) words after "date assigned."

PART 456—UTILIZATION CONTROL—Continued

New section	Old section
456.235	450.19(a)(2)(iii)(B) and (iv).
456.236	450.19(a)(2)(ix)(B), (C) 1st and 2d sentences, (D)–(G) words before "and written notification", and (H) words before "written notification."
456.237	450.19(a)(2)(ix)(G) words after "considered final" and (H) words after "mental hospital services."
456.238	450.19(a)(2)(ix)(A).
456.241	450.19(a)(2)(x)(A) 1st and 2d sentence.
456.242	450.19(a)(2)(iii)(A), (x)(B), and (xi).
456.243	450.19(a)(2)(x)(A) 3d and 4th sentences.
456.244	450.19(a)(2)(x)(A) last sentence words before "and (B)."
456.245	450.19(a)(2)(x)(A) 5th sentence.
456.260	450.18(a)(2).
456.270	450.23(a)(1) introductory paragraph 1st and 2d sentences, (i) and (iv).
456.271	450.18(a)(1)(v) last sentence.
456.280	450.18(a)(3)(ii), (iv), 450.23(a)(1) introductory paragraph 1st and 2d sentences and (ii).
456.281	450.18(a)(3)(iv), 450.23(a)(1)(iii).
456.301	450.19(a) introductory paragraph except "hospital, mental hospital" and "intermediate care facility."
456.302	450.19(a)(3) introductory paragraph.
456.305	450.19(a)(3)(ii) introductory paragraph and (v).
456.306(b) and (c)	450.19(a)(3)(ii)(A) and (B).
456.311	450.19(a)(3)(vii), (viii) introductory paragraph words after "such application" and before "and is either:"; and (ix)(C) words after "is appropriate" and before "At the expiration."
456.312	450.19(a)(3)(vi).
456.313	450.19(a)(3)(i).
456.331	450.19(a)(3)(viii) words before "on or before a specified date."
456.332	450.19(a)(3)(ix)(B) 2d sentence except words "and closer professional scrutiny."
456.333	450.19(a)(3)(viii)(A) words before "but at least."
456.334	450.19(a)(3)(viii)(A) words after "functional capabilities", (B), and (ix)(C) words after "date assigned."
456.335	450.19(a)(3)(iii)(B) and (iv).
456.336	450.19(a)(3)(ix)(A), (B) words before "The single State agency", (C), (D), (E), (F) words before "and written notification", and (G) words before "written notification."
456.337	450.19(a)(3)(ix)(F) words after "shall be considered final" and before "not later than" and words after "the assigned review date", and (G) words after "nursing facility services" and before "not later than" and words after "assigned review date."
456.338	450.19(a)(3)(ix)(F) words after "shall be sent except (*1*)–(*4*), and (G) words "shall be made" except (*1*)–(*4*).
456.341	450.19(a)(3)(x)(A) 1st and 2d sentences.
456.342	450.19(a)(3)(iii)(A), (x)(B).
456.343	450.19(a)(3)(x)(A) 3d and 4th sentences.
456.344	450.19(a)(3)(x)(A) 6th sentence.
456.345	450.19(a)(3)(x)(A) 5th sentence.
456.346	450.18(a)(1)(iv).
456.347	450.18(a)(1)(iv).
456.348	450.18(a)(1)(iv).
456.360	450.18(a)(2).
456.370	450.24(a)(1)(i)(A)–(C) 1st sentence.
456.371	450.24(a)(1)(i)(C) 2d sentence.
456.372	450.18(a)(1)(v) last sentence.
456.380	450.18(a)(3)(ii), 450.24(a)(1)(ii).
456.381	450.24(a)(1)(iii).
456.401	450.19(a) introductory paragraph first word, words after "skilled nursing facility and", (4) 2d sentences except (i)–(vii).
456.402	450.19(a)(4) introductory paragraph parenthetica note.
456.405	450.19(a)(4)(ii)(A) 1st sentence except words "and by whom."

PART 456—UTILIZATION CONTROL—Continued

New section	Old section
456.406	450.19(a)(4)(ii)(A) words after "How, when, and."
456.407	450.19(a)(4)(ii)(B).
456.411	450.19(a)(4)(v) and (vii)(C) words after "determined and" and before "in accordance with."
456.412	450.19(a)(4)(iv).
456.413	450.19(a)(4)(i).
456.431	450.19(a)(4)(vi) words before "or more frequently" and words after "time of assessment."
456.432	450.19(a)(4)(vii)(B) 2d sentence except words "and closer professional scrutiny."
456.433	450.19(a)(4)(vi) 1st sentence, words after "for continued stay."
456.434	450.19(a)(4)(vi) 1st sentence, words after "for continued stay" and (vii)(C) words after "date assigned."
456.435	450.19(a)(4)(iii).
456.436	450.19(a)(4)(vii)(A)–(F) words before "and written notification" and (G) words before "written notification."
456.437	450.19(a)(4)(vii)(F) words after "shall be considered final" to words before "not later than" and words after final determination, and (G) words after "intermediate care facility services" and before "not later than" and words after "such final determination."
456.438	450.19(a)(4)(vii)(F) words after "shall be considered final" except (*1*)–(*4*), and (G) words after "intermediate care facility services" except (*1*)–(*4*).
456.481	450.23(a)(1) 3d sentence.
456.482	450.23(a)(1) 3d sentence.
456.501	450.20(c) 1st sentence.
456.505	450.19(b) 1st sentence.
456.506	450.19(b) 6th to 8th sentences; and 450.20(c) 2d to 4th sentences.
456.507	450.19(b) 2d and 3d sentences.
456.508	450.19(b) 4th sentence.
456.520	450.19(c)(1)(i).
456.521	450.19(c)(2), (5) 1st sentence, and (6).
456.522	450.19(c)(3), (4), and (7).
456.523	450.19(c)(5) 2d sentence and (8) 2d sentence.
456.524	450.19(c)(8) 1st sentence and (9) 1st sentence.
456.525	450.19(c)(9) 2d and 3d sentences.
456.601	450.24(a) parenthetical note.
456.602	450.23(a)(2)(i) and (ii) and 450.24(a)(2)(i).
456.603	450.23(a)(2)(iii) and 450.24(a)(2)(ii).
456.604	450.23(a)(3)(ii) and 450.24(a)(3)(ii).
456.605	450.23(a)(3)(i) and 450.24(a)(3)(i).
456.606	450.23(a)(3)(iii) and 450.24(a)(3)(iii).
456.607	450.23(a)(3)(iii) and 450.24(a)(3)(iv).
456.608	450.23(a)(3)(v) 1st and 2d sentences and 450.24(a)(3)(v) 1st 3 sentences.
456.609	450.23(a)(3)(v) 3d sentence and 450.24(a)(3)(v) 4th sentence.
456.610	450.23(a)(3)(v)(A)–(F) and 450.24(a)(3)(v)(A)–(G).
456.611	450.23(a)(4)(i) and 450.24(a)(4)(i).
456.612	450.23(a)(4)(ii) and 450.24(a)(4)(ii)
456.613	450.23(a)(4)(iii) and 450.24(a)(4)(iii).
456.614	450.23(b) and 450.24(c).

Redesignation Table IV

This redesignation table has been developed as a reference tool only. The redesignations of specific sections and paragraphs from 45 CFR Parts 205, 206, and 208 apply only to the Medicaid program. The regulatory provisions under Parts 205, 206, and 208 that apply to the financial assistance programs (Title I, IV-A, X, XIV, and XVI of the Social Security Act) and the social services programs (title XX of the Act) remain in these parts; published at 44 FR 17927, Mar. 23, 1979.

Cross Reference: This table corrected at 45 FR 24882, Apr. 11, 1980, as seen in Redesignation Table VI of this Finding Aids section.

Old Section in 45 CFR	New Section in 42 CFR
205.10(a) to words before "where a State agency adopts."	431.205.
205.10(a)(1)(ii) words after "right of appeal to a State agency hearing"	431.206.
205.10(a)(1)(ii) words after "* * * 397 U.S. 254 (1970)	431.202.
205.10(a) (2)–(3)	431.206.
205.10(a)(4)(i)(A)	431.211.
205.10(a)(4)(i)(B)	431.210.
205.10(a)(4)(ii) words before "or of the AFDC * * *"	431.213.
205.10(a)(4)(ii) words after "* * * death of a recipient * * *" to words before "(B) the agency * * *"	Deleted—unnecessary.
205.10(a)(4)(ii) (B), (C), (E), (F), (H)	431.213.
205.10(a)(4)(ii) (D), (G), (I)	Deleted—unnecessary.
205.10(a)(4)(iii)	431.206; 431.210.
205.10(a)(4)(iv)	431.214.
205.10(a)(5) to words before "* * * unless the reason for * * *"	431.220.
205.10(a)(5) words after "* * * classes of recipients * * *" to words before "* * * (i) A request * * *".	Deleted—unnecessary.
205.10(a)(5) (i), (ii), and (iii)	431.221.
205.10(a)(5)(iv)	431.222.
205.10(a)(5)(v) to words before "* * * where the sole issue is one * * *" Also words after "* * * action for such refusal.".	431.223.
205.10(a)(5)(v) words after "* * * by the claimant in writing," to words before "* * * or where it is abandoned".	Deleted—unnecessary.
205.10(a)(6)(i)(A) to words before "* * * and not one of incorrect grant * * *"	431.230 (a)(1) and (b).
205.10(a)(6)(i)(A) words after "* * * change in State or Federal Law * * * to words before "(ii) The agency shall * * *".	Deleted—unnecessary.
205.10(a)(6)(ii)	431.230(a)(2).
205.10(a)(6)(iii) to words before "Unless a de novo * * *" and words after "* * * substantial evidence in the record".	431.232.
205.10(a)(6)(iii) words after "right to request a de novo hearing * * *" to words before "assistance shall not be * * *".	431.233.
205.10(a)(7)	431.231.
205.10(a) (8)–(10)	431.240.
205.10(a)(11) to words before "In respect to title IV-C."	431.243.
205.10(a)(11) words after "* * * in the conduct of the hearing"	Not applicable to Medicaid.
205.10(a)(12) to words before "* * * or in making a payment,"	431.241.
205.10(a)(12) words after "* * * decision on eligibility * * *" to words before "(ii) Agency * * *".	Deleted—unnecessary.
205.10(a)(12)(ii), introductory paragraph, (A), and (B) first word and words after "* * * of financial or * * *" and before "or change".	431.241.
205.10(a)(12)(ii)(B) words after "Amount" and before "* * * medical assistance * * *" and words after "* * * medical assistance".	Not applicable to Medicaid.
205.10(a)(12)(ii)(C)	Not applicable to Medicaid.
205.10(a)(13) to words before "(ii) At his * * *"	431.242.
205.10(a)(13)(i)	431.242(a).
205.10(a)(13)(ii)	Deleted—redundant.
205.10(a)(13)(iii)	431.242(b).

Redesignation Table IV

Old Section in 45 CFR	New Section in 42 CFR
205.10(a)(13)(iv)	431.242(c).
205.10(a)(13)(v)	431.242(d).
205.10(a)(13)(vi)	431.242(e).
205.10(a) (14)–(16)	431.244.
205.10(a)(17)	431.245.
205.10(a)(18)	431.246.
205.10(a)(19)	431.244.
205.10(b) (1)–(2)	431.250.
205.10(b)(3)	Deleted—unnecessary.
205.10(b)(4)	431.250.
205.30	431.15.
205.50(a) words before "(A) The administration * * *"	431.301.
205.50(a)(1)(i)(A) after words "such purposes include"	431.302 (a)–(c).
205.50(a)(1)(i)(B)	431.302(d).
205.50(a)(1)(i)(C)	Not applicable to Medicaid.
205.50(a)(1)(ii)	431.303.
205.50(a)(1)(iii)	431.306(c).
205.50(a)(2)	431.305(a).
205.50(a)(2)(i)	431.305(b).
205.50(a)(2)(ii)	431.306(b).
205.50(a)(2)(iii)	431.306(d).
205.50(a)(2)(iv)	431.306(f).
205.50(a)(2)(v)	431.306(e).
205.50(a)(3)	431.304.
205.50(a)(4)	431.307.
205.50(b)	431.301.
205.50(c)	Not applicable to Medicaid.
205.50(d)	Not applicable to Medicaid.
205.60(a)(1)	431.17 (b)–(c).
205.60(a)(2)	431.16.
205.60(b)	431.17(d).
205.70(a)	431.18(c).
205.70(b) (1)–(2)	431.18(d).
205.70(c) words before "* * * and will establish * * *"	431.18 (e) and (g).
205.70(c) words after "* * * or to prepare for a fair hearing; * * *"	431.18(f).
205.100(a)(1) (i)–(ii)	431.10(b).
205.100(a)(2)(i)	431.10(c).
205.100(a)(2)(ii)	431.10(d).
205.100(b)	431.10(e).
205.101(c)(1)	431.11(b).
205.101(c) (2)–(3)	431.11(c).
205.101(c)(4)	431.11(d).
205.120(a)	431.50(b).
205.120(b)	431.50(c).
205.130(a)(1)	433.33(a).
205.130(a)(2)	433.33(c)(1).
205.145 to words before "Under this requirement * * *"	433.32(a).
205.145 words after "* * * in accord with applicable Federal requirements." and (a).	433.32(b).
205.145(b)	433.32(c).
205.145(c)	433.32(d).
205.150(a)(1)	433.34(b) through (d)(1).
205.150(a)(1)(i) words before "(The estimated costs are included * * *)"	433.34(d) (2)–(4).
205.150(a)(1)(i) words after "* * * activities with justification for each; * * *," to words before "(ii)".	433.34(e)(3).
205.150(a)(1)(ii)	433.34(d)(5).
205.150(a)(1)(iii)	433.34(d)(6).
205.150(a)(2)	433.34(e)(1).
205.150(b)(1)	433.34(f)(1).
205.150(b)(2)	433.34(f)(2).
205.150(b)(3)	433.34(f)(3).
205.150(b)(4)	433.34(f)(4).
205.150(b)(5)	433.34(e)(2).
205.150(b)(6)	433.34(f)(5).
205.160(a)	433.35(c).
205.160(a) (1) through (3)	433.35(d).
205.160(b) (1) and (2), first sentence	433.35(b).
205.160(b)(2), second and third sentences	433.35(f)(1).
205.160(b)(3)	433.35(f)(2).
205.160(c)(1)	433.35(e).
205.160(c)(2)	433.35(f)(3).
205.160(c)(3)	433.35(f)(3).
205.170	Deleted—unnecessary

Old Section in 45 CFR	New Section in 42 CFR
206.10(a)(1)(i)	435.906 and 436.901.
206.10(a)(1)(ii)	435.907 and 436.901.
206.10(a)(1)(iii)	435.906 and 436.901.
206.10(a)(1)(iv) (A) and (B)	435.909 and 436.909.
206.10(a)(1)(iv)(C)	435.907 and 436.901.
206.10(a)(1)(v) (A) and (C)	435.910 and 436.901.
206.10(a)(1)(v)(B)	Not applicable to Medicaid.
206.10(a)(2)(i)	435.905 and 436.901.
206.10(a)(2)(ii)	435.916(b) and 436.901.
206.10(a)(3)	435.911 and 436.901.
206.10(a)(4)	435.912 and 436.901.
206.10(a)(5)	435.930 and 436.901.
206.10(a)(6)(i)	Not applicable to Medicaid.
206.10(a)(6)(ii)	435.914 and 436.901.
206.10(a)(7)	435.919 and 436.901.
206.10(a)(8)	435.913 and 436.901.
206.10(a)(9) (i) and (ii)	435.916(c) and 436.901.
206.10(a)(9)(iii) words before "* * * and every 12 months * * *"	Not applicable to Medicaid.
206.10(a)(9)(iii) words after "* * * than every 6 months in AFDC * * *"	435.916(a) and 436.901.
206.10(a)(9)(iii) (A) and (B)	435.920 and 436.901.
206.10(a)(10)	435.902 and 436.901.
206.10(a)(11)	435.903 and 436.901.
206.10(a)(12)	435.904 and 436.901.
206.10(b)(1)	Redundant—430.1.
206.10(b)(2)	Redundant—435.907.
208.1(a)	441.101.
208.1(a)(1)	431.620.
208.1(a)(2)	441.102(a).
208.1(a)(2)(i), first sentence	441.102(b)(2).
208.1(a)(2)(i), second sentence	441.102(b)(1).
208.1(a)(2)(ii)	441.102(b)(4).
208.1(a)(2)(iii)	441.102(b)(3).
208.1(a)(2)(iv)	441.102(b)(5).
208.1(a)(3) and (4)	441.103.
208.1(a)(5) and (6)	441.105.
208.1(a)(7)	441.106.
208.1(b)	Not applicable to Medicaid.

Derivation Table

This list includes only new sections based on regulations existing before redesignation. Sections containing new material that is introductory or explanatory have not been included.

New Section in 42 CFR	Old Section in 45 CFR
431.10	205.100.
431.11	205.101.
431.15	205.30.
431.16	205.60(a)(2).
431.17	205.60(a) (1) and (b).
431.18	205.70.
431.50	205.120.
431.202	205.10(a) (Introductory paragraph).
431.205	205.10(a)(1).
431.206	205.10(a) (2) and (3).
431.210	205.10(a)(4)(i)(B).
431.211	205.10(a)(4)(i)(A).
431.213	205.10(a)(4)(ii).
431.214	205.10(a)(4)(iv).
431.220	205.10(a)(5).
431.221	205.10(a)(5) (i)–(iii).
431.222	205.10(a)(5)(iv).
431.223	205.10(a)(5)(v).
431.230	205.10(a)(6).
431.231	205.10(a)(7).
431.232	205.10(a)(6)(iii) (1st Sentence).
431.233	205.10(a)(6)(iii) (2nd Sentence).

Redesignation Table IV

New Section in 42 CFR	Old Section in 45 CFR
431.240	205.10(a) (8)–(10).
431.241	205.10(a)(12) (i) and (ii)(B).
431.242	205.10(a)(13).
431.243	205.10(a)(11) (1st Sentence).
431.244	205.10(a) (14), (15) and (16).
431.245	205.10(a)(17).
431.246	205.10(a)(18).
431.250	205.10(b).
431.301	205.50(a)(1)(i)(A) (1st Sentence) and 205.50 (b) and (c).
431.302	205.50(a)(1)(i)(A) (2nd Sentence).
431.303	205.50(a)(1)(ii).
431.304	205.50(a)(3).
431.305	205.50(a)(2)(i).
431.306	205.50(a)(2) (ii)–(v).
431.307	205.50(a)(4).
431.620	208.1(a)(1).
433.32	205.145.
433.33	205.130.
433.34	205.150.
433.35	205.160.
435.902	206.10(a)(10).
435.903	206.10(a)(11).
435.904	206.10(a)(12).
435.905	206.10(a)(2)(i).
435.906	206.10(a)(1) (Introductory paragraph).
435.907	206.10(a)(1)(ii) (words before "from the applicant").
435.908	206.10(a)(1)(ii) (words after "State agency") and (iii).
435.909	206.10(a)(1)(iv) (A) and (B).
435.910	206.10(a)(1)(v) (A) and (C).
435.911	206.10(a)(3).
435.912	206.10(a)(4).
435.913	206.10(a)(8).
435.914	206.10(a)(6).
435.916	206.10(a)(2)(ii) and 206.10(a)(9) (i)–(iii).
435.919	206.10(a)(7).
435.920	206.10(a)(9)(iii) (A) and (B).
435.930	206.10(a)(5).
436.901	206.10.
436.909	206.10(a)(1)(iv) (A) and (B).
441.101	208.1(a) (words before "(1) Having in effect * * *").
441.102	208.1(a)(2).
441.103	208.1(a) (3) and (4).
441.105	208.1(a) (5) and (6).
441.106	208.1(a)(7).

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Redesignation Table V

At 45 FR 22935, Apr. 4, 1980, certain sections of regulations formerly appearing in Title 42 as Part 405 were redesignated as Part 489.

For the convenience of the user, the following tables show the relationship of the redesignated sections.

PART 456—UTILIZATION CONTROL

Old 42 CFR Part 405	New 42 CFR Part 489
405.602	489.10.
405.603	489.12.
405.604(a)(1)	489.15(b).
405.604(a)(2)	489.15(c).
405.604(b)	489.15(d).
405.604(c)(1)	489.16(a).
405.604(c)(2)	489.16(c).
405.604(c)(3)	489.16(b)(1) and (2).
405.604(d)	Deleted as outdated.
405.605	489.2(b) & (c).
405.606(a)	489.11(a).
405.606(b)	489.11(b) & (c).
405.606(c)	489.53.
405.607(a)	489.21(a).
405.607(b)	489.20(b).
405.607(c)	489.20(c).
405.608	489.30.
405.609	489.31.
405.610(a)	489.32.
405.610(b)	489.22.
405.612	489.21(b).
405.613	489.52.
405.614	489.53.
405.615	489.55.
405.616	489.57.
405.617	489.50.
405.618	489.40.
405.619	489.35.
405.620(a)	489.41(c).
405.620(b)	489.41(a).
405.620(c)	489.41(b).
405.620(d)	Deleted as unnecessary.
405.621	489.41(a).
405.622	489.42.
405.625(a)	Superseded by 489.18(b) (c) and (d).
405.625(b)	Deleted because of change in policy.
405.626(a)	489.18(a)(1).
405.626(b)	489.18(a)(2).
405.626(c)	489.18(a)(3).
405.626(d)	489.18(e).

Derivation Table

New 42 CFR Part 489	Old 42 CFR Part 405
489.1	New.
489.2(a)	405.601, 1st sentence.
489.2(b) and (c)	405.605.
489.3	New.
489.10	405.602.
489.11(a)	405.606(a).
489.11(b) and (c)	405.606(b).
489.12	405.603.
489.13	405.606.
489.15(a)	405.604, introductory paragraph.
489.15(b)	405.604(a)(1).
489.15(c)	405.604(a)(2).
489.15(d)	405.604(b).
489.16(a)	405.604(c)(1).
489.16(b)(1) and (2)	405.604(c)(3).
489.16(c)	405.604(c)(2).
489.18(a)(1)	405.626(a).
489.18(a)(2)	405.626(b).
489.18(a)(3)	405.626(c).
489.18(a)(4)	405.626(d).
489.18(b)	405.625(b).
489.18(c) and (d)	405.625(a) with substantive change.
489.18(e)	405.626(d).
489.20(a)	405.607(a).
489.20(b)	405.607(b).
489.20(c)	405.607(c).
489.21(a)	405.607(a)(1).
489.21(b)(1)	405.612(a)(2).
489.21(b)(2)	405.612(a)(3).
489.21(b)(3)	405.612(a)(4).
489.21(b)(4), 1st sentence	405.607(a)(2) and 405.612.
489.21(b)(4), 2nd sentence	405.612(b).
489.21(c)	405.607(a)(3).
489.21(d)	405.607(a)(4).
489.22	405.610(b).
489.30	405.608.
489.31	405.609.
489.32	405.610(a).
489.35	405.619.
489.40	405.618.
489.41(a)	405.620(b) and 405.621
489.41(b)	405.620(c).
489.41(c)	405.620(a).
489.42	405.622.
489.50	405.617.
489.52(a)	405.613(a), 1st and 2nd sentences.
489.52(b)(1)	405.613(a), 3rd and 4th sentences.

Derivation Table—Continued

New 42 CFR Part 489	Old 42 CFR Part 405
489.52(b)(2)	405.613(b), except for last sentence.
489.52(b)(3)	405.613(c).
489.52(c)	405.613(a), last two sentences and 405.613(b), last sentence.
489.53	405.614.
489.55	405.615.
489.57	405.616.

Redesignation Table VI

The following table, published at 45 FR 24882, Apr. 11, 1980, reflects corrections to Redesignation/Derivation Table IV, published at 44 FR 17927, Mar. 23, 1979.

Corrected Redesignation Table

New section	Old section
448.2(b)	435.401(c)(1).
448.3(c)(1)(iv)	435.840.
448.3(c)(3)(ii)	435.831(a) (2), (3), 435.845(d), (e).
449.33(a)(5)	431.610(g).
449.33(b)(2)	431.610(h).
450.25	431.800.
450.30(a)(2) (words "provide for...").	447.251.
450.30(a)(3) (Introductory paragraph, words after "cost-related basis").	447.301.
450.30(a)(3) (words "provide for").	447.251.
450.30(a)(4) (words "provide for").	447.251.
450.30(a)(10)	447.371.
450.30(b)(4)(i)	447.351.
450.30(b)(4)(ii), and (iii)	447.352.
450.30(b)(5)	447.321, 447.325.
450.100	431.610 except (g) & (h).
450.310	455.300.

Corrected Derivation Table

New section	Old section
431.610 except (g) & (h)	450.100.
431.610(g)	449.33(a)(5).
431.610(h)	449.33(b)(2).
431.800	450.25.
435.110	448.1(b)(1)(i).
435.401	448.2(a) & (b).
435.831	448.1(a)(2)(ii), (b)(3)(v), (5)(iv), (c)(2), (3), (4).
447.251 (covers the previous State Plan requirement in 450.30(a)(2), hospitals, (a)(3), long term care services, and (a)(4), upper limits for all services.	450.30(a)(2), 450.30(a)(3), 450.30(a)(4).
447.301	450.30(a)(3). Introductory paragraph, words afte "cost-related basis," and 450.30(a)(3)(iv).
447.325	450.30(b)(5).
447.351	450.30(b)(5)(i).
447.352	450.30(b)(4)(ii) and (iii).
447.361	450.30(b)(7).
447.371	450.30(a)(10).

Redesignation Table VII

At 45 FR 42179, June 23, 1980, certain sections of regulations formerly in Title 42 as Part 405 were redesignated as Part 421.

For the convenience of the user, the following table shows the relationship of the redesignated sections.

Old section	NPRM section	New section
405.651(a), 405.652, 405.653	419.13	421.104.
405.651(b)	419.3(c)	421.5(c).
405.651(c)	419.3(b)	421.5(b).
405.651(d)	419.3(a)	421.5(a).
405.654	419.12	421.103.
405.655	419.14	421.105.
405.656	419.13	421.104.
405.660	419.25	421.110.
405.662, 405.663	419.30	421.126.
405.670, 405.677, 405.678	419.40	421.200.
405.671	419.2	421.3.
405.672	419.3(a)	421.5(a).
405.673	419.41	421.202.
405.675	419.44	421.204.
405.676	419.45	421.205.

Redesignation Table VIII

At 46 FR 55696, November 12, 1981, certain sections of regulations formerly in Title 20 as Part 422 were redesignated and transferred to Title 42 as Part 401.

For the convenience of the user, the following table shows the relationship of the redesignated sections.

Old section	NPRM section
20 CFR 422.401	42 CFR 401.101(a)(2)
422.402	401.102
422.406	401.106
422.408	401.108
422.410	401.110
422.412	401.112
422.416	401.116
422.418	401.118
422.420	401.120
422.426	401.126
422.428	401.128
422.430	401.130
422.432	401.132
422.433	401.133
422.434	401.134
422.435	401.135
422.436	401.136
422.440	401.140
422.444	401.144
422.448	401.148
422.452	401.152

Redesignation Table IX

At 48 FR 12534, Mar. 25, 1983, certain sections of regulations formerly appearing in Title 42 as Part 405 were redesignated as Part 409.

For the convenience of the user, the following table shows the relationship of the redesignated sections.

Old section	New section
405.101(a)	409.3.
405.101(b)	Deleted.
405.102	408.10.
405.103	408.11.
405.104	408.13.
405.105	408.12.
405.106 (a) & (b)	408.20.
405.106 (c) & (c)(1)	408.21.
405.106(c)(2)	408.25.
405.106(c)(3)	Deleted as unnecessary. § 405.210 clearly applies only to individuals already entitled to Hospital insurance. Reference to § 405.106 must be deleted from § 405.205.
405.106(d)	408.22.
405.110(a)	Deleted as inaccurate and unnecessary.
405.110(a) (1) & (2)	409.61(a)(1).
405.110(b)	409.3.
405.110(c)(1)	Deleted as outdated.
405.110(c)(2)	Deleted as redundant.
405.110(d)	409.62(a).
405.111 Uncoded introduction.	Deleted as unnecessary.
405.111(a)	409.63(a).
405.111(b)	Deleted as outdated.
405.111 (c) & (d)	409.63(a).
405.112	409.64.
405.113	409.80.
405.114	409.87.
405.115	409.82.
405.116	409.10.
405.116(a)	409.10.
405.116(b)	409.11.
405.116(c)	409.12.
405.116(d)(1)	409.13.
405.116(d)(2)	409.14.
405.115(e)	409.16.
405.116(f)	409.15.
405.116(g) and (h)	409.18.
405.117	409.89.
405.118(a) language through "paragraph (c) of this section"	409.65(b).
405.118(a) remaining language	409.65(a).
405.118(b)	409.65(c).
405.118(c)	409.65(d).
405.118(d)	409.65(e).
405.119	409.66.
405.120(a)(1) words "he was an inpatient for not less than 3 consecutive days".	409.30(a).
405.120(a)(1) all other words.	Deleted because mostly cross-references or duplicative of content of § 409.30.
405.120(a)(2) First 2 sentences.	Deleted as outdated.
405.120(a)(2) Last sentence.	Deleted as unnecessary. The cited § 405.152 takes care of the matter.
405.120(b)(1)	Deleted because 100-day limitation is explained in § 409.61(b).
405.120(b)(2)	409.32.
405.120(b)(3)	Deleted because the specifics of the cited sections are incorporated in § 409.31.
405.120(c)	409.30(a).
405.120(d)(2) Words through the 3rd and final "October 30, 1972".	Deleted as unnecessary. Since (d)(1), which dealt with admissions *before* 10/30/72, was deleted, there is only one set of requirements.
405.120(d)(2) remaining words through (d)(2).	409.30(b).
405.120(d)(3) Words through the parenthetical statement.	Deleted as unnecessary (a calendar day is a calendar day).
405.120(d)(3) Remaining words.	409.32.
405.120(e) Deductible and coinsurance amount.	§§ 409.80 and 409.82.
405.122	409.64.
405.123	409.87.
405.124	409.85.
405.125	409.20.
405.126 Uncoded introduction.	Deleted as unnecessary.
405.126 (a) & (b)	409.31.
405.127(a)	409.31.
405.127(b)	409.32.
405.127 (c) & (d)	409.33.
405.128	409.34.
405.128a	409.35.
405.130	409.44.
405.131 Uncoded introduction (and specifics taken from 405.236).	409.40(a).
405.131(a)–(f)	409.40(b).

Old section	New section
405.133	Deleted because Section 941 of Pub. L. 96-499 revoked the presumed coverage provisions of the Act.
405.151	409.69.
405.161	409.68.
405.180	408.30.
405.181	408.31
430.1	400.200 and 400.203.

Redesignation Table X

At 50 FR 1345 Jan. 10, 1985, certain sections of regulations formerly appearing in Title 42, Part 405, Subpart T were redesignated as Part 417.

For the convenience of the user, the following table shows the relationship of the redesignated sections.

Old section	New section
405.2001	417.201
405.2002	417.202
405.2003	417.203
405.2004	417.204
405.2005	417.205
405.2007	417.207
405.2020	417.220
405.2021	417.221
405.2022	417.222
405.2023	417.223
405.2024	417.224
405.2025	417.225
405.2028	417.228
405.2029	417.229
405.2030	417.230
405.2031	417.231
405.2032	417.232
405.2033	417.233
405.2034	417.234
405.2035	417.235
405.2036	417.236
405.2037	417.237
405.2038	417.238
405.2039	417.239
405.2040	417.240
405.2041	417.241
405.2042	417.242
405.2043	417.243
405.2044	417.244
405.2045	417.245
405.2046	417.246
405.2047	417.247
405.2049	417.249
405.2050	417.250
405.2051	417.251
405.2052	417.252
405.2053	417.253
405.2054	417.254
405.2056	417.256
405.2058	417.258
405.2059	417.259
405.2060	417.260
405.2061	417.261
405.2062	417.262
405.2063	417.263
405.2065	417.265
405.2066	417.266
405.2067	417.267
405.2068	417.268
405.2069	417.269
405.2070	417.270
405.2071	417.271
405.2072	417.272
405.2073	417.273
405.2074	417.274
405.2075	417.275
405.2076	417.276
405.2077	417.277
405.2078	417.278
405.2079	417.279
405.2080	417.280
405.2081	417.281
405.2082	417.282
405.2083	417.283
405.2084	417.284
405.2085	417.285
405.2086	417.286
405.2087	417.287
405.2088	417.288
405.2089	417.289
405.2090	417.290
405.2091	417.291
405.2092	417.292
405.2093	[1] 417.800
405.2094	417.802
405.2095	417.804
405.2096	417.806
405.2097	417.808
405.2098	417.810

[1] Section 417.801 was redesignated from 42 CFR 405.692.

Redesignation Table XI

At 50 FR 12741 Mar. 29, 1985, certain sections of regulations formerly appearing in Title 42 as Part 405 were redesignated as Part 412.

For the convenience of the user, the following table shows the relationship of the redesignated sections.

Old paragraph	New paragraph or section
405.470(a)(1)	412.1(a)
405.470(a)(2)	412.1(b)
405.470(b)(1)	412.2(a)
405.470(b)(2)	412.2(b)
405.470(b)(3)	412.2(c)
405.470(b)(4)	412.2(d)
405.470(b)(5)	412.2(e)
405.470(c)(1)	412.4(a)
405.470(c)(2)	412.4(b)
405.470(c)(3)	412.4(c)
405.470(c)(4)	412.4(d)
405.470(d)(1)	412.6(a)
405.470(d)(2)	412.6(b)
405.470(e)(1)	412.8(a)
405.470(e)(2)	412.8(b)
405.471(a)(1)	412.20(a)
405.471(a)(2)	412.20(b)
405.471(b)(1)	412.22(a)
405.471(b)(2)	412.22(b)
405.471(b)(3)	412.22(c)
405.471(c)(1)	412.23(a)
405.471(c)(2)	412.23(b)
405.471(c)(3)	412.23(c)
405.471(c)(4)(i)	412.25(a)
405.471(c)(4)(ii)	412.27
405.471(c)(4)(iii)	412.29
405.471(c)(4)(iv)	412.32
405.471(c)(5)	412.23(d)
405.471(c)(6)	412.23(e)
405.471(c)(7)	412.23(f)
405.471(c)(8)	412.23(g)
405.471(d)	412.23(b)(8)
405.471(e)(1)	412.30(a)
405.471(e)(2)	412.30(b)
405.471(f)	412.25(b)
405.472(a)(1)	412.40(a)
405.472(a)(2)	412.40(b)
405.471(b)(1)	412.42(a)(2)
405.472(b)(1)(i)	412.42(a)(2)(i) and 412.42(b)
405.472(b)(1)(ii)	412.42(b)(2)
405.472(b)(1)(iii)	412.42(c)
405.472(b)(1)(iv)	412.42(d)
405.472(b)(1)(v)	412.42(e)
405.472(b)(1)(vi)	412.42(f)
405.472(b)(2)	412.42(g)
405.472(b)(3)	412.42(a)(1)
405.472(c)	412.44
405.472(d)(1)	412.45
405.472(d)(2)	412.46
405.472(e)	412.48
405.472(f)	412.50
405.472(g)	412.52
405.473(a)(1)	412.60(a)
405.473(a)(2)	412.60(b)
405.473(a)(3)	412.60(c)
405.473(a)(4)	412.60(d)
405.473(b)(1)	412.62(a)
405.473(b)(2)	412.62(b)
405.473(b)(3)	412.62(c)
405.473(b)(4)	412.62(d)
405.473(b)(5)	412.62(e)
405.470(b)(6)	412.62(f)
405.473(b)(7)	412.62(g)
405.473(b)(8)	412.62(h)
405.473(b)(9)	412.62(i)
405.473(b)(10)	412.62(j)
405.473(b)(11)	412.62(k)
405.473(c)(1)	412.63(a)
405.473(c)(2)	412.63(b)
405.473(c)(3)	412.63(c)
405.473(c)(4)	412.63(d)
405.473(c)(5)	412.63(e)
405.473(c)(6)	412.63(f)
405.473(c)(7)	412.63(g)
405.474(a)(1)	412.71(a)
405.474(a)(2)	412.70(b)
405.474(a)(3)	412.70(c)
405.474(a)(4)	412.70(d)
405.474(b)(1)	412.71(a)
405.474(b)(2)(i)	412.71(b)
405.474(b)(2)(ii)	412.71(c)
405.474(b)(3)(i)	412.71(d)
405.474(b)(3)(i)(A)	412.72(a)(1)
405.474(b)(3)(i)(B)	412.72(a)(2)
405.474(b)(3)(i)(C)(1)	412.72(a)(3)(i)
405.474(b)(3)(i)(C)(2)	412.72(a)(3)(ii)
405.474(b)(3)(i)(D)	412.72(a)(4)
405.474(b)(3)(i)(E)	412.72(a)(5)
405.474(b)(3)(ii)	412.72(b)
405.474(b)(4)	412.73(a)
405.474(b)(5)	412.73(b)
405.474(b)(6)	412.73(c)
405.474(b)(7)	412.73(d)
405.474(b)(8)	412.73(e)
405.474(c)(1)	412.74(a)
405.474(c)(2)	412.74(b)
405.474(d)	412.76
405.475(a)(1)	412.80(a)
405.475(a)(2)	412.80(c)
405.475(b)	412.80(d)
405.475(c)(1)	412.82(a)
405.475(c)(2)	412.82(b)
405.475(c)(3)	412.82(c)
405.475(c)(4)	412.82(d)
405.475(d)(1)	412.84(a)
405.475(d)(2)	412.84(b)

Redesignation Table XI

Old paragraph	New paragraph or section
405.475(d)(3)	412.84(c)
405.475(d)(4)	412.84(d)
405.475(d)(5)	412.84(e)
405.475(d)(6)	412.84(f)
405.475(e)	412.80(e)
405.476(a)	412.90
405.476(b)(1)	412.92(b)(1) and (b)(2)
405.476(b)(2)	Removed as duplicative of § 405.473(b)(6)
405.476(b)(3)(i)	412.92(b)(4)
405.476(b)(3)(ii)	412.92(a)
405.476(b)(4)&(b)(5)	412.92(c)
405.476(b)(6)	412.92(b)(3)
405.476(c)	412.92(d)
405.476(d)	412.92(e)
405.476(e)	412.98
405.476(f)(1)	412.94(a)
405.476(f)(2)	412.94(b)
405.476(g)(1)	412.96(a)
405.476(g)(1)(i)&(ii)	412.96(b)
405.476(g)(1)(iii)	412.96(c)
405.476(g)(2)(i)	412.96(d)
405.476(g)(2)(ii)	412.96(e)
405.476(g)(3)	412.96(f)
405.476(h)	412.100
405.476(i)(1)	412.102(a)
405.476(i)(2)	412.102(b)
405.476(j)(1)	412.104(a)
405.476(j)(2)	412.104(b)
405.477(a)	412.110
405.477(b)	412.112
405.477(c)	412.113
405.477(d)(1)&(d)(2)(i)	412.115
405.477(d)(2)(ii)	412.118(a)
405.477(d)(2)(iii)	412.118(b)
405.477(d)(2)(iv)	412.118(c)
405.477(d)(2)(v)	412.118(d)
405.477(d)(2)(vi)(A)	412.118(e)
405.477(d)(2)(vi)(B)	412.118(e)
405.477(d)(2)(vi)(C)	412.118(f)
405.477(e)(1)	412.120(a)
405.477(e)(2)	412.120(b)
405.477(e)(3)	412.120(c)
405.477(f)	412.125

Redesignation Table XII

At 51 FR 22042, June 17, 1986, certain sections of regulations formerly appear-ing in Title 42, Part 405, Subpart J were redesignated as Part 482.

For the convenience of the user, the following table shows the relationship of the redesignated sections.

Old Part 405	New Part 482
405.1011	482.2
405.1020	482.11
405.1021(a)–(d)	482.12
405.1021(e)	482.12(a)
405.1021(f) & (g)	482.12(b)
405.1021(h)	482.12(c)
405.1021(i)	482.41
405.1021(j)	482.12(d)
405.1022	482.41 and 482.42
405.1023	482.22
405.1024 except (d)	482.23
405.1024(d)	482.51
405.1025	482.28
405.1026	482.24
405.1027	482.25
405.1028	482.27
405.1029	482.26
405.1030	Deleted
405.1031(a)	482.51
405.1031(b)	482.52
405.1031(c)	Deleted as duplicative of 482.22
405.1031(d)	482.5
405.1032	482.5
405.1033	482.12
405.1034	Delete Provisio included a part o 482.21(
405.1035	482.3
405.1036	482.6
405.1037	482.6
405.1038	482.6
405.1039	Delete Provision removed b la
405.1040	Delete Provision removed b la
405.1041	482.6
405.1042	482.3

Redesignation Table XIII

At 52 **FR** 22446, June 12, 1987, certain sections of regulations appearing in Title 42, Part 405, Subparts F and O were redesignated as Part 498 of Title 42.

For the convenience of the user, the following table shows the relationship of the redesignated sections.

Old section	New section
405.640	498.20(a)(2)
405.685	405.1902(b)
405.1501(a)	Removed as duplicative of § 405.1502.
405.1501(b), (c), and (e).	498.5
405.1501(d)	498.3(e)
405.1502	498.3(b)
405.1503	498.20(a)
405.1504	498.20(b)
405.1505	498.3(c)
405.1510	498.22(a)
405.1511(a)	498.22(c)
405.1511(b)	498.22(b)
405.1512	498.22(b)(2)
405.1513	498.23
405.1514	498.24
405.1515	498.24
405.1516	498.25(a)
405.1517	498.25(b)
405.1518	498.22(d)
405.1519	498.30
405.1520	498.32(a)
405.1521	498.32(b)
405.1530	Removed as duplicative of § 405.1531.
405.1531	498.40
405.1532	498.42
405.1533	498.44
405.1534	498.45
405.1535	498.47
405.1536	498.48
405.1537	498.49
405.1538	498.50
405.1539	498.50
405.1540	498.52
405.1541	498.53
405.1542	498.56
405.1543	498.54
405.1544	498.58
405.1545	498.60
405.1546	498.61
405.1547	498.62
405.1548	498.63
405.1549	498.64
405.1550	498.66
405.1551	498.68
405.1552	498.69
405.1553	498.70
405.1554	498.71
405.1555	498.71
405.1556	498.72
405.1557	498.74
405.1558	498.74
405.1559	498.76
405.1560	498.78
405.1561	498.80
405.1562	498.82
405.1563	498.83
405.1564	498.85
405.1565	498.86
405.1566	498.88
405.1567	498.90
405.1568	498.83
405.1569	498.95
405.1570	498.100
405.1571	498.102
405.1572 and 405.1571(c).	498.103
405.1590	498.10
405.1591	498.11
405.1592	498.13
405.1593	498.15
405.1594	498.11(b)
405.1595	498.17.

Redesignation Table XIV

At 53 FR 23100, June 17, 1988, §§ 405.1901—405.1913 (Subpart S), formerly appearing in Title 42, Part 405, were redesignated as Part 488 of Title 42.

For the convenience of the user, the following table shows the relationship of the redesignated sections.

REDESIGNATION TABLE

Old section	New section
Part 405	Part 488
Subpart S	Subpart A
405.1901(a)	488.01
405.1901 (b) and (c)	488.03
405.1901(d)	488.05
405.1901(e)	488.06
405.1901(g)	488.08
405.1902(a)	488.10
405.1902(b)	488.11
405.1902(c)	488.12
405.1902(d)	488.14
405.1903	488.18
405.1904	488.20
405.1905	488.24
405.1906	488.26
405.1907	488.28
	Subpart B
405.1908	488.50
405.1909	488.52
405.1910	488.54
405.1911	488.56
405.1912	488.60
405.1913	488.64
	Subpart C
	488.100
	488.105
	488.110
	488.115

Derivation Table I

At 51 FR 34764, Sept. 30, 1986, a document was published by the Department of Health and Human Services which established in Title 42 a new Chapter V, Office of Inspector General—Health Care, consisting of Parts 1000 through 1004. This document also removed Part 101 from Title 45. A second document at 51 FR 34786, Sept. 30, 1986 amended Title 42, Parts 412, 420, 455, 466, 474, and 489.

This table identifies the sections of 42 CFR Chapter IV and 45 CFR Subtitle A from which the new 42 CFR Chapter V derives its content. In the case of Title 45, all of the source sections were redesignated. In the case of 42 CFR Chapter IV, some of the source sections were redesignated, but others were retained in Chapter IV and duplicated in Chapter V.

New Section	Source Section
	42 CFR Chapter IV
1001.1	420.1
1001.2	420.2
1001.3	420.3
1001.100	420.100
1001.101	420.101
1001.102	420.102
1001.103	420.103
1001.105	420.105
1001.107	420.107
1001.109	420.109
1001.114	420.114
1001.115	420.115
1001.122	420.122
1001.123	420.123
1001.124	420.124
1001.125	420.125
1001.126	420.126
1001.128	420.128
1001.130	420.130
1001.132	420.132
1001.134	420.134
1001.136	420.136
1001.201	489.54
1001.211	489.55
1001.221	489.57
1001.301	412.48(c), (d), and (e)
1002.1	455.1
1002.2	455.2
1002.3	455.106
1002.200	455.200
1002.203	455.203
1002.204	455.204
1002.205	455.205
1002.206	455.206
1002.207	455.207
1002.208	455.208
1002.210	455.210
1002.211	455.211
1002.212	455.212
1002.213	455.213
1002.214	455.214
1002.230	455.230
1002.232	455.234
	42 CFR Chapter IV
1002.234	455.234
1002.301–1002.321	455.300
	45 CFR Subtitle A
1003.100	101.100
1003.101	101.101
1003.102	101.102
1003.103	101.103
1003.104	101.104
1003.105	101.105
1003.106	101.106
1003.107	101.107
1003.108	101.108
1003.109	101.109
1003.110	101.110
1003.111	101.111
1003.112	101.112
1003.113	101.113
1003.114	101.114
1003.115	101.115
1003.116	101.116
1003.117	101.117
1003.118	101.118
1003.119	101.119
1003.120	101.120
1003.122	101.122
1003.123	101.123
1003.124	101.124
1003.125	101.125
1003.126	101.126
1003.127	101.127
1003.128	101.128
1003.129	101.129
1003.130	101.130
1003.131	101.131
1003.132	101.132
1003.133	101.133
	42 CFR Chapter IV
1004.1	474.0
1004.10	474.30
1004.20	474.32
1004.30	474.34
1004.40	474.36

New Section	Source Section
	42 CFR Chapter IV
1004.50	474.38
1004.60	474.39
1004.70	474.40
1004.80	474.41
1004.90	474.42
1004.100	474.52
1004.110	474.54
1004.120	474.56
1004.130	474.58

Derivation Table II

At 53 FR 36571, Sept. 21, 1988, the Department of Health and Human Services revised Part 430. The following derivation table identifies the sections of 45 CFR Chapter IV from which 42 CFR Chapter IV derives its content.

New Section	Source Section
(42 CFR Ch. IV)	(45 CFR Ch. II)
430.10	201.2.
430.12(a)	204.2.
430.12(b)	201.3(a) and 204.1
430.12(c)	201.3 introductory statement, 204.2, and 205.5(a)
430.14	201.3(b).
430.15(a)	201.3(d).
430.15(b)	201.3(c) first sentence.
430.15(c)	201.3(c) second sentence.
430.16(a)	201.3 (e) and (f).
430.16(b)	201.3(c) third sentence.
430.18(a)	201.4 first sentence.
430.18(b)	201.4 second and third sentences.
430.18(c)	201.4 fourth sentence.
430.18(d)	201.4 fifth sentence.
430.18(e)	201.4 sixth sentence.
430.20	201.3(g) and 205.5(b).
430.30(a)	201.5 introductory statement.
430.30(b)	201.5(a) (1) and (2).
430.30(c)	201.5(a)(3).
430.30(d)	201.5 (b), (c) and (d).
430.30(e)	201.5(e).
430.32(a)	201.10(a).
430.32(b)	201.10(b).
430.32(c)	201.13(b).
430.33 (a) and (b).	201.12.
430.33(c)	201.13.
430.35 (a)–(c)	201.6 (a), (c), and (d).
430.35(d)	201.6(e).
430.38	201.7.
430.40	201.15(c).
430.42	201.14 (b), (c) and (e) and 204.4.
430.45	201.14(a).
430.48	201.66.
430.60	213.1.
430.62	213.2.
430.63	213.5.
430.64	213.4.
430.66	213.21.
430.70	213.11.
430.72	213.12 and 213.13.
430.74	213.14.
430.76	213.15.
430.80	213.22.
430.83	213.23.
430.86	213.23a.
430.88	213.24 and 213.25.
430.90	213.26.
430.92	213.27.
430.94	213.28.
430.96	213.29.
430.100	213.31.
430.102	213.32 (a), (b), and (d).
430.104	213.32(c) and 213.33.

Table 1—20 CFR Part 405 List of CFR Sections Affected for 1973 to 1977

EDITORIAL NOTE: At 42 FR 52826, September 30, 1977, regulations formerly appearing in Title 20 as Part 405 were redesignated and transferred into Title 42 as Part 405.

The following list of CFR sections affected contained in this Appendix formerly appeared in Title 20 and is updated through September 30, 1977.

1973

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Chapter III
405 Nomenclature changes...3597, 26718
Heading revised............................13637
405.104 Added..................................17211
405.116 (g) added.............................17211
405.231 (g) and (h) revised...........17211
405.316 (a) and (b) revised........... 13637
405.317 Revised.............................. 13637
405.318 Revised.............................. 13638
405.319 Revised.............................. 13638
405.320 Revised.............................. 13639
405.321 Added..................................13639
405.402 (g) added.............................17211
405.405 Heading revised; (d) removed.. 14093
405.406 (a) revised; (c), (d), and (e) added.. 6387
(e) corrected..........................7223, 7458
405.419 (c)(4) removed................. 14093
405.429 (b)(2) revised....................14093
405.454 (k) added............................ 6387
(a), (g), (h), and (k) revised.........14093
405.502 (e) added............................17212
405.603 Added..................................6387
405.622 Added..................................3598
405.1201—405.1230 (Subpart L) Revised..18978
405.1203 Added..............................23325
405.1204 Added..............................23325
405.1205 Added..............................23326
405.1206 Added..............................23326
405.1207 Added..............................23326
405.1208 Added..............................23326
405.1505 (g) added...........................3598

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Chapter III
405.116 (f) revised......................... 32328
405.153 Revised.............................. 1750
405.214 (a) and (b) revised............. 2757
405.226 Added...................................2757
405.231 (h) and (l) revised............28624
405.232 (e) revised..........................28624
405.232a Added..............................23624
405.232b Added..............................28621
405.232c Added..............................28624
405.239 Revised............................. 19483
405.240 (d) revised.........................19483
405.243 (b) example revised.........19483
405.244 (c) revised......................... 19483
405.245 Revised............................. 19483
405.310 (i) revised..........................28625
405.313 Revised.............................. 1750
405.401—405.488 (Subpart D) Heading revised........................ 34515
405.401 (a) revised............16883, 20164
405.402 (a) revised............16883, 20165
405.421 (e) revised..........................32328
405.451 (a) revised..........................16883
405.455 Added.................................16883
(d)(1) amended; (d)(2) revised....20165
405.460 Added.................................20165
405.461 Added.................................20166
405.461 (b)(3)(i) corrected........... 22415
405.490—405.499i Removed.........34515
405.522 (a), (b) and (c) revised.... 32328
405.525 Revised............................. 32329
405.601—405.685 (Subpart F) Heading revised.......................... 2239
405.601 Amended............................ 2239
405.602 Amended............................ 2239
405.604 Added...................................2239

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Chapter III—Continued	39 FR Page
405.605 Revised	2239
405.606 (b) revised; (c) added	2240
405.607 Introductory text of (a) revised	20167
405.613 (a) revised	2240
405.614 (a) revised	2240
405.615 (a) revised	2240
405.616 Revised	2240
405.685 (d) added	2240
405.801 Revised	12096
405.802 (b) through (f) revised	12096
405.803 Revised	12097
405.805—405.823 Revised	12097
405.820 Revised	12097
405.832 (d) redesignated as (e); new (d) added	12098
405.841 Revised	12098
405.842 (b) revised	12098
405.902 (a) revised	3933
405.904 (c) revised	14589
405.905 Removed	14589
405.911 (a) amended	14589
405.913 (b), (c), and (d) revised	14589
405.915 (b)(3) revised	14590
405.916 Revised	14590
405.921 (b) revised	14590
405.927 (a) revised	14590
405.929 Added	14590
405.936 Revised	14590
405.947 (b) revised	14590
405.960 (a)(2) revised	14590
405.964 Added	14591
405.1001 Removed	2251
405.1002 Removed	2251
405.1003 Removed	2251
405.1004 Removed	2251
405.1005 Removed	2251
405.1006 Removed	2251
405.1007 Removed	2251
405.1008 Removed	2251
405.1009 Removed	2251
405.1010 Removed	2251
405.1035 (a), (d)(4) and (5), (e), (f), and (g) revised; (b) amended; (j) and (k) added	41605
405.1101—405.1137 (Subpart K) Revised	2240
405.1101 (f) revised	35775
405.1121 (i) revised; (k) added; (l) redesignated from § 405.1122	35775
405.1122 Redesignated as § 405.1121(l)	35775
Added	35776
405.1124 Introductory text, (c), and (g) revised	35776

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Chapter III—Continued	39 FR Page
405.1126 Introductory text and (a) revised	35777
405.1134 (j) revised	35777
405.1137 (h) added	35777
Introductory text and (a) through (e) revised; (i) added	41607
405.1203 Removed	2251
405.1204 Removed	2251
405.1205 Removed	2251
405.1206 Removed	2251
405.1207 Removed	2251
405.1208 Removed	2251
405.1301 Removed	2251
(b) (39 FR 2251) reinstated	27795
405.1302 Removed	2251
405.1303 Removed	2251
405.1304 Removed	2251
405.1305 Removed	2251
405.1306 Removed	2251
405.1307 Removed	2251
405.1308 Removed	2251
405.1309 Removed	2251
405.1310—405.1317 (Subpart M) Revised	33692
Effective date corrected	36579
405.1310 Revised	3369
405.1315 Revised	33692
405.1401 Removed	2251
405.1402 Removed	2251
405.1403 Removed	2251
405.1404 Removed	2251
405.1405 Removed	2251
405.1406 Removed	2251
405.1407 Removed	2251
405.1408 Removed	2251
405.1409 Removed	2251
405.1501 Revised	2249
405.1502 Amended; (b)(2) revised	2250
405.1503 Revised	2250
405.1505 Revised	225
405.1510 Amended	225
405.1511 (b) revised	225
405.1513 Amended	225
405.1514 Amended	225
405.1515 Amended	225
405.1518 Amended	225
405.1519 Revised	225
405.1531 Revised	225
405.1532 Revised	225
405.1537 Amended	225
405.1542 (a) amended	225
(b) revised	225
405.1544 Revised	22

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Chapter III—Continued

		39 FR Page
405.1545	Amended	2251
405.1550	Revised	2251
405.1560	Revised	2251
405.1563	Revised	2251
405.1590	Amended	2251
405.1591	Amended	2251
405.1627	(a)(3) revised	28625
405.1660	(a) and (c) revised	36470
405.1662	Revised	36470
405.1663	Revised	36470
405.1664	Introductory text and (d) revised	36470
405.1665	Introductory text revised	36470
405.1666	Revised	36471
405.1667	Revised	36471
405.1672	(a) and (b) revised	36471
405.1675	(a)(1) revised	3934
405.1680	Revised	3934
405.1692	Revised	36471
405.1693	Revised	36472
405.1694	Revised	36472
405.1801—405.1889	(Subpart R) Added	34515
405.1901—405.1910	(Subpart T) Added	2251
	Redesignated as Subpart S	11419
405.1911	Added	35777

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Chapter III

		40 FR Page
405.102	Revised	24357
405.103	Revised	24358
405.104	Revised	24358
405.105	Added	24359
405.106	Added	24359
405.116	(g) revised	17747
405.120	(a)(1) amended; (d) revised	23289
405.126	Revised	43896
405.127	Revised	43897
405.128	Revised	43898
	Corrected	46309
405.128a	Added	43898
405.129	Removed	1023
405.195	Added	1023
405.196	Added	1023
405.201—405.252	(Subpart B) Appendix added	17747
405.205	Revised	18165
405.210	Revised	18166
405.213	Text designated as (a); (b) added	18166

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		40 FR Page
405.214	(d) added	18166
405.217	(b) introductory text and (c)(1) revised; (g) through (i) added	43211
405.221	(e) added	18166
405.222	(c) revised	43212
405.223	(e) added	18166
	(c) revised	43212
405.230	(a)(2) and (5) revised	44321
405.231	(g) and (h) revised	17747
	(l) revised; (m) added	44321
405.232	(e) revised; (j) added	44321
405.236	(b) revised	44321
405.239	Revised	44322
405.250	(b)(3) revised	44322
405.250a	Added	44322
405.301	Revised	1023
405.310	Introductory text revised	1023
	Introductory text (m) and (n) added	24360
405.315a	Added	36314
405.315b	Added	36315
405.330	Added	1024
405.331	Added	1024
405.332	Added	1024
405.402	(c) introductory text revised	32743
	(c)(9) added	33440
405.415	(k) added	32743
405.419	(e) added	32743
405.429	(b)(3) added	32743
405.430	(a), (c)(1), (d)(1) and (2), and heading of (e)(1) revised	22540
405.432	Added	5761
405.433	Added; eff. 4-26-76	34513
405.435	Added	32743
405.454	(j) added	29816
405.460	(e) revised	32744
405.465	Added	33440
405.466	Added	33443
405.502	(a) revised	25447
405.504	(a) revised	25447
405.512	Added	7639
405.521	(d) redesignated as (d)(1); (d)(2) and (3) added	33443
405.614	(a)(4) and (c) revised; (a)(5) added	36315
405.702	Revised	1024
405.704	Revised	1025
405.705	(e) added	53386
405.708	Revised	1025
405.710	Revised	1025
405.714	Revised	1025

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405.715 Revised	1025
405.716 Revised	1025, 53387
405.717 Revised	1025, 53387
405.718—405.718e Added	53387
405.720 Revised	1025
405.722 Revised	1026
405.730 Revised	1026, 53387
405.740 (h) added	1026
405.745 Revised	1026
405.803 (b) revised	1026
405.820 (b)(4) added	1026
405.902 (b) introductory text and (b)(1) and (2) revised; example 4 added	18166
405.912 (b) revised	11865
405.1021 (i)(3) removed; (j) added	24324
405.1022 (b) revised	26656
405.1035 Effective date postponed	14592
(e)(6)(ii) amended	14592
(e) and (f) effective date postponed	28052, 33033, 42006
405.1121 Introductory text and (f) revised	24325
405.1137 Effective date postponed	14592
(d)(2) amended	14592
405.1221 (i) added	24325
(a) and (h) revised	56661
405.1310 (a) and (d) revised	3765
405.1315 (c)(3) revised	3766
405.1501—405.1595 (Subpart O) Heading revised	36315
405.1501 Heading, (a) and (b) revised; (f) added	36315
405.1502 (e) added	36316
405.1503 Revised	36316
405.1504 Revised	36316
405.1505 Introductory text and (k) added	36316
405.1519 Revised	36316
405.1530 Revised	36316
405.1531 Revised	36316
405.1532 Revised	36316
405.1534 Revised	36316
405.1536 Revised	36317
405.1537 Revised	36317
405.1542 (a) revised	36317
405.1543 Revised	36317
405.1545 Revised	36317
405.1550 Revised	36317
405.1551 Revised	36317
405.1552 Revised	36318

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	41 FR Page
Chapter III	
405 Effective date corrected	41912
405.133 Added	21341
(a) corrected	22560
405.165 Revised	21344
405.170 (b)(3) and (4) revised; (c) added	21344
405.232 (e)(2)(iii) revised	20871
405.251 (b)(4)(ii) and (iii) revised; (b)(4)(iv) added	1492
405.350 Revised	1492
405.352 Introductory text revised	1492
405.355 Revised	1492
405.371 (c) revised	52050
405.402 (g) revised	49594
405.419 (a) and (b)(2)(iii) revised	52050
405.429 Revised	46292
405.432 (f)(3) added	49594
405.433 Effective date extended to 8-26-76	16968
(c) revised	49594
405.454 (l) added	52050
405.455 (a) revised	49594
405.460 (f)(5) added	49595
405.502 (e) revised	49595
405.607 (a)(3) revised; (a)(4) added	149
405.711 Revised	47917
405.717 Revised	47917
405.718a (b)(1) and (3) revised	47917
405.722 Revised	47917
Nomenclature change	51588
405.730 Nomenclature change	51588
405.740 Nomenclature change	51588
405.741 Nomenclature change	51588
405.747 Nomenclature change	51588
405.750 Nomenclature change	51588
405.1024 (b) amended	2796
405.1031 Introductory text revised	2250
405.1201—405.1230 (Subpart L) Appendix amended	1789
405.1230 Revised	2087
405.1310 (m) added	2251
405.1314 (b)(13) added	2251
405.1317 (b)(8) added	2251
405.1501—405.1595 (Subpart O) Heading revised	84
405.1501 Heading, (a) and (c) revised	84
405.1502 (b) revised	84
405.1503 Revised	84

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Chapter III—Continued

405.1505 (a) revised....8482
405.1510 Revised....8482
405.1511 (a) revised....8482
(b) revised....47918
405.1512 Revised....8482
405.1513 Revised....8482
405.1515 Revised....8482
405.1516 Revised....8483
405.1519 Revised....8483
405.1520 Revised....8483
405.1530 Revised....8483
405.1531 Revised....8483
(a) revised....47918
405.1532 Revised....8483
405.1534 Revised....8483
405.1536 Revised....8483
405.1537 Revised....8484
405.1542 (a) revised....8484
405.1543 Revised....8484
405.1545 Revised....8484
405.1550 Revised....8484
405.1551 Revised....8484
405.1552 Revised....8485
405.1556 Revised....54753
405.1562 (a) revised....54753
405.1632 (a) and (c) revised....21344
405.1633 (a)(2) and (b) revised....21345
405.1701—405.1737 (Subpart Q) Heading and text revised....20865
405.1845 (d) revised....52051
405.1871 (b) revised....52051
405.1875 Revised....52051
405.1877 Revised....52051
405.1901 (c) and (d) redesignated as (d) and (e); new (c) added....22510
405.1910 (c) amended....27962
405.1912 Added....22510
405.2040 Added....49595

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405.2041 Added....49595
(d) corrected....53320
405.2042 Added....49596
(c)(2) corrected....53320
405.2043 Added....49598
(e) table corrected....53320
405.2044 Added....49600
405.2045 Added....49600
405.2046 Added....49601
405.2047 Added....49601
405.2049—405.2053 Added....49602
405.2054 Added....49604
(c) corrected....53320
405.2059 (c) and (j) revised....47918
405.2060 (d) revised....47918
405.2065—405.2092 Added....39308
405.2100—405.2171 (Subpart U) Added....22511

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405 Redesignated as 42 CFR 405....52825
405.415 (d)(1), (2), and (3) headings added, (d)(3) existing text designated as (d)(3)(i) and heading added; (d)(3)(ii) added....45897
405.504 (a)(2) and (3)(i) and (ii) revised....18275
405.1035 (l) added....1029
405.1625—405.1697 (Subpart P) Heading revised....44220
405.1695 Added....44220
405.1696 Added....44220
405.1697 Added....44220

Table 2—45 CFR Parts 246 and 248 Through 252 List of CFR Sections Affected for 1973 to 1977

EDITORIAL NOTE: At 42 FR 52827, September 30, 1977, regulations formerly appearing in Title 45 as Parts 246, 248, 249, 250, 251 and 252 were redesignated and transferred into Title 42 as Parts 446, 448, 449, 450, 451 and 452, respectively. The following list of CFR sections affected contained in this table formerly appeared in Title 45 and is updated through September 30, 1977.

1973

45 CFR

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Chapter II

248.10 (a)(1), (b)(2)(ii) and (iv), and (d)(1) and (2) revised; (b)(3) and (4) redesignated as (b)(5) and (6); (b)(5) redesignated as (b)(7) and revised; new (b)(3) and (4) added..........33380
248.21 (a) revised; (b) redesignated as (c) and revised; new (b) added..........33382
248.30 (b)(1) revised..........33382
248.50 Revised..........30259
248.60 (a)(1), (2), and (3)(iv) revised..........33383
Effective date corrected..........31174
249.10 (b)(4)(i) heading and introductory text revised..........12112
249.33 (a)(1)(vii) and (c)(2) revised..........21413
249.81 Revised..........33383
252.10 (b)(1), (c)(2)(iii), and (d) revised..........12112
252.20 Removed..........12113

1974

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Chapter II

248.1 Added..........9513
248.2 Added..........9515
248.3 Added..........9516
(b)(5) and (c)(2)(i) and (ii) amended..........36590
248.4 Added..........9517
248.10 Introductory text added..........9518

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Chapter II—Continued

(b)(4) revised..........16971
248.11 Existing text designated as (b); (a) added..........9518
248.21 (a) revised..........5552
Introductory text added..........9518
(a)(3)(ii)(A) and (B) amended..........36590
248.30 Revised..........9518
248.50 Revised..........9518
248.60 (a)(1) revised; (b)(9) and (10) added..........2221
248.70 Revised..........9518
248.80 Revised..........9518
(c) corrected..........10253
249.10 (b)(14) and (c) revised; (b)(15) redesignated as (b)(17), new (b)(15) added; (b)(16) reserved; (d)(1)(iv), (v), and (vi) added..........2221
(b)(4)(i) revised..........2257
(b)(15)(i)(*e*), (ii) introductory text, (ii)(*a*), (iii)(*b*) and (d)(1)(vi) corrected..........3918
(a)(1), (2), (5), and (6) and (b)(7), (11), and (17) revised; (a)(9) removed; new (a)(9) and (10) added..........16971
(a)(3) revised..........27906
(b)(6) revised..........37637
(b)(4)(i)(B) revised; (b)(15)(vi) added..........40019
(b)(1) and (14)(i)(A) revised..........41611
249.11 Redesignated as 249.20..........2223
249.12 Added..........2223
(a)(1)(ii)(B) and (9)(iii) and (c)(2) and (3)(v) corrected..........8918
249.13 Added..........2226

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Chapter II—Continued
(c)(6)(ii)(C)(*1*) and (12)(ii)(E) corrected; (h)(i) through (x) correctly designated as (h)(1) through (10); (h)(10) revised........8918
249.20 Redesignated from 249.11 and revised........2223
249.31 Added........12866
249.32 Revised........16972
249.33 Revised........2254
(a)(1)(i), (iii), (2), (4)(iii)(B), and (8)(i)(B) corrected........8918
(a)(3)(i) revised........16972
(a)(1) amended........41611
249.40 Revised........5553
(a)(2) and (b) revised........36590
(a)(2)(ii) table corrected........39267
249.41 Revised........16972
250.18 Added........41611
250.19 Added........41612
250.20 Amended; (a)(3) added.....35778
Revised........41617
250.23 Amended........41618
(a)(1)(ii) revised; (b)(2) removed; (b)(1) redesignated as (b); (c) added........41618
250.24 Added........2234
(a)(1) and (3)(v)(B) corrected...... 8918
(a)(1)(ii) revised........41618
250.30 (a)(6) revised; (b)(3)(iii) added........2235
(b) and (d) revised........21135
(a) (2) through (7) redesignated as (a) (3) through (8); new (a)(2) added; (b) introductory text and (b)(1) revised........28288
(b) revised........31639
(b) and (d) revised........43632
250.70 Added........16973
250.80 Revised........7930
250.90 Added........17763
(b)(2)(ii) corrected........22269
250.100 Added........2256
250.120 Revised........16973
(d) amended........36590
250.220 (Subpart C) Added........31528
(b)(4) corrected........32739

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Chapter II
248.1 (a)(3) added; (b)(3) revised........52020
248.10 (b)(3) revised........52020

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Chapter II—Continued
248.70 (a)(2) and (3) and (c)(1) revised........25819
249.10 (b)(1) and (14) effective date stayed........14597
(b)(4)(i) revised........43901
(c)(3) removed; (c)(4) added...... 28793
249.33 (a)(1)(i) effective date stayed........14597
(a)(7) removed........28793
249.82 Revised........20517
250.18 Effective date stayed........14597
(a)(1)(iii) revised........30819
250.19 Effective date stayed........14597
(a) amended........14597
(a)(1)(viii) effective date postponed........28071, 33033, 33036
(c) added........30819
249.20 Revised........52020
250.23 Effective date stayed........14597
250.24 (a)(1)(ii) effective date stayed........14597
250.25 Added........27221
250.30 (b)(3)(iii) revised........14598
(b)(3)(iii) revised........15388
(b)(2) revised........34519
(d) revised........52021
(b)(2)(ii) revised........5400

1976

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Chapter II
248.1(c)(iv) revised........22055
248.10 (b)(2)(iv) revised........22055
248.60 (a)(2) and (a)(3)(iv) revised........22055
249.10 (b)(16) added (c)(1) and (2) revised; (c)(5) added........219
(a)(6)(iii) revised........22055
(a)(4) and (b)(7) revised; eff. 11-23-76........3584
249.12 (a)(1)(ii) and (c)(6) revised........1288
249.13 Introductory text revised........1286
249.31 Revised; eff. 10-26-76........3620
250.18 (f) redesignated from 250.20(b)(2) and revised........2367
250.20 (b)(2) revised and redesignated as 250.18(f)........2367
250.23 Revised........22
(a)(1) introductory text, (i), and (iv) amended........2205
250.30 (b)(3)(ii) revised........22

45 CFR—Continued

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Chapter II—Continued

Eff. date extended to 8-26-76.... 16968
(a)(3) through (8) redesignated and revised as (a)(4) through (9); new (a)(3) added................ 27305
(b) amended.................................. 27307
(a)(2)(i) and (iii) and (b)(1) revised...51402
(a)(3)(iii)(B)(*1*) and (*4*), (a)(3)(iv) introductory text and (A) amended...................... 53994
250.80 (a)(5) revised......................13585
(a)(4) revised; (b) redesignated as (c); new (b) added................26221
250.210 Added; interim rule effective date 12-31-72................48738

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Chapter II

246 Redesignated as 42 CFR Part 446..52827
246.160 Added....................................33293
248 Redesignated as 42 CFR Part 448..52827
248.3 (b)(1), (2), and (3) revised; (b)(4), (5), and (6) redesignated as (b)(7), (8), and (9); new (b)(4), (5), and (6) added............2686
248.21 (a)(2) revised........................2687
249 Redesignated as 42 CFR Part 449..52827

45 CFR—Continued

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Chapter II—Continued

249.10 (d)(3) added..........................4125
(b)(15)(i)(D) revised.....................15064
Nomenclature change................. 43977
249.12 (c)(6) revised...................... 15064
(c)(3)(ix) added 28702
249.13 Introductory text revised..15064
(b)(6)(i) and (xi) revised.............28703
249.33 (a)(8) and (a)(8)(i)(B) revised...15064
(a)(2), (a)(4)(iii) introductory text and (A), (iv) introductory text, and (5)(iv) revised; (a)(8) removed..28703
249.82 Effective date changed to 8-9-76...51584
Nomenclature change.................43977
250 Redesignated as 42 CFR Part 450..52827
250.25 Revised..................................37208
250.30 (a)(3)(iii)(B)(*1*) and (*4*), (a)(3)(iv) introductory text and (A) corrected..........................779
(d)(2) revised..................................46537
Nomenclature change................43977
250.70 (a)(2) amended................. 43977
250.80 Nomenclature change...... 43977
250.210 Added; final rule............ 23509
251 Redesignated as 42 CFR Part 451..52827
252 Nomenclature change........... 43977
Redesignated as 42 CFR Part 452...52827

Table 3—42 CFR Part 101 List of CFR Sections Affected for 1973 to 1977

EDITORIAL NOTE: At 42 FR 52826, September 30, 1977, regulations formerly appearing in Title 42 as Part 101 were redesignated and transferred into Parts 460 through 480 of this title.

The following list of CFR sections affected contained in this table formerly appeared in Title 42 (1 to 399) and is updated through September 30, 1977.

1973

(No regulations published)

1974

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	39 FR Page
Chapter I	
101 Added	10205
101.7 Amended	23060
101.36 Amended	23060
101.37 Amended	23060
101.101—101.106 (Subpart B) Added	16202

1975

(No regulations published)

1976

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	41 FR Page
Chapter I	
101.2a Added	33436
101.101 (a) amended; (c) added	17865

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	41 FR Page
Chapter I—Continued	
101.103 Amended	17865
101.104 Introductory text revised	17865
101.1401—101.1406 (Subpart N) Added	7878
101.2101—101.2106 (Subpart U) Added	28687

1977

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	42 FR Page
Chapter I	
101 Redesignated as Title 42 Parts 460-480	52826
101.27 Revised	48337
101.39 Revised	42858, 43084
101.1401—101.1406 (Subpart N) Revised	4677

List of CFR Sections Affected

All changes in this volume of the Code of Federal Regulations which were made by documents published in the FEDERAL REGISTER since January 1, 1977, are enumerated in the following list. Entries indicate the nature of the changes effected. Page numbers refer to FEDERAL REGISTER pages. The user should consult the entries for chapters and parts as well as sections for revisions.

For a complete "List of CFR Sections Affected" before the recodification at 42 FR 52826, September 30, 1977, see Tables 1, 2 and 3; and for the period before January 1, 1973, see the "List of CFR Sections Affected, 1949-1963, and 1964-1972," published in three separate volumes.

1973

(No regulations published)

1974

(No regulations published)

1975

(No regulations published)

1976

(No regulations published)

1977

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Chapter IV
Chapter added.....52826
446—452 (Subchapter C) Added.....52826
446 Redesignated from 45 CFR Part 246.....52826
Nomenclature changes.....65116
446.10 (Subpart A) Heading added; section heading revised.....60564
446.150—446.185 (Subpart B) Added.....60564
448 Redesignated from 45 CFR Part 248.....52826
Nomenclature changes.....65116
449 Redesignated from 45 CFR Part 249.....52826
Nomenclature changes.....65117
449.10 (a)(11) added.....64345
450 Redesignated from 45 CFR Part 250.....52826
Nomenclature changes.....65119
450.120 (Subpart B) Removed.....60566

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Chapter IV—Continued
451 Redesignated from 45 CFR Part 251.....52826
452 Redesignated from 45 CFR Part 252.....52826
Nomenclature changes.....65120
460—480 (Subchapter D) Added.....52827
460 Redesignated from 101.1—101.56 (Subpart A).....52827
Nomenclature changes.....65121
460.36 Amended.....59086
461 Redesignated from 101.101—101.107 (Subpart B).....52827
Nomenclature changes.....65121
462—472 Redesignated from Part 101 Subparts C-M and Reserved.....52826
473 Redesignated from 101.1401—101.1406 (Subpart N).....52827
Nomenclature changes.....65121
474—479 Redesignated from Part 101 (Subparts O-T) and Reserved.....52826
478 Added.....62276
480 Redesignated from 101.2101—101.2106 (Subpart U).....52827
Nomenclature change.....65122

1978

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Chapter IV
430 Added.....45187
431 Added.....45188
432 Added.....45199

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Chapter IV—Continued
433 Added.......45201
435 Added.......45204
436 Added.......45218
440 Added.......45224
441 Added.......45229
441.250—441.259 (Subpart F) Added.......52171
442 Added.......45233
446 Removed.......45187
447 Added.......45253
448 Technical correction.......6605
Removed.......45187
448.1 (c)(4) revised.......7986
(a)(1), (b)(2)(i), (c)(1), and (d) revised; (b)(1)(vii) and (viii) added; eff. in part 7-1-77.......9813
(d) and (e) technical correction.......20009
(a)(1)(ii) and (b)(2)(viii)(D) revised.......44530
448.2 (d)(4) and (e) revised.......9814
448.3 (b)(1)(ii) and (7) through (9) revised; eff. in part 7-1-77.......9814
(b)(1)(ii)(7) technical correction.......20009
448.4 (a) and (b)(3) revised; (e) added; eff. in part 7-1-77.......9815
448.10 (b)(2)(iv) revised.......7986
(b)(2)(i) and (ii), and (d) revised.......9815
(b)(2) technical correction.......20009
448.21 (a)(2)(i)(C), (3)(i)(B) and (C) and (c) revised.......9815
Introductory text technical correction.......20009
448.60 (a)(2) and (3)(iv) revised.......7986
(a)(1) and (b)(3) revised; (b)(11) added; eff. 10-1-76.......9816
(b)(11) revised.......20009
448.70 (a)(1) amended.......9816
448.80 (a)(1) amended.......9816
449 Technical correction.......6605
Removed.......45137
449.10 (a)(6)(iii), (b)(16)(ii) and (iii)(A) and (C) revised.......7986
(c)(1) revised.......9816
(b)(2) existing text redesignated as (b)(2)(i); (b)(2)(ii) and (iii) added.......30527
449.31 Revised.......8801
449.41 (c)(1) revised; eff. 7-1-77.......9816
449.82 Revised.......5828

42 CFR—Continued

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Chapter IV—Continued
449.100—449.109 (Subpart A) Added.......4580
Republished.......4842
449.103 Revised.......31878
449.104 Revised.......31878
449.105 Revised.......31878
450 Technical correction.......6605
Removed.......45187
450.23 (a)(1) introductory text, (i) and (iv) amended.......7986
450.25 Revised.......13575
450.30 Clarification.......4861
(a)(2) revised.......8804
(a)(10) added.......30527
(b)(4) revised.......32300
450.80 (a)(8) and (d) added.......3120
(a)(6) revised.......9817
(a)(8)(i) revised.......32081
450.90 (b)(2) introductory text and (v) revised.......9817
450.310 (Subpart D) Added.......3120
(a)(5) and (6) and (f)(5) and (6) added; (c), (f)(2), (h)(1)(vii), (i)(1)(iv) and (v), (j)(1), (2)(iii), and (5) revised.......32081
451 Removed.......45187
452 Removed.......45187
455 Added.......45262
456 Added.......45266
460.2 Revised.......29006
460.7 Amended.......55936
460.11 Revised.......2630
460.24 Amended.......2630
460.36 Amended.......59086
460.37 Revised.......46307
460.48 Revised.......44531
462 Added.......32085
463 Added.......7407
476 Added.......2283
478.101—478.106 (Subpart B) Added.......854
481 Added.......5375
481.2 Introductory text, and (a) through (d) revised.......30528
481.8 (a) revised.......3052
481.9 (a), (b), and (c) revised.......30528
481.10 (a), (b), and (c) revised.......30529

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Chapter IV
430.0 (b)(3) revised.......1792
431.10 Added.......1793

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Chapter IV—Continued

431.11 Added....17931
431.15 Added....17931
431.16 Added....17931
431.17 Added....17931
431.18 Added....17931
431.50 Added....17931
431.107 Revised: eff. 10-15-79....41644
431.115 Heading and (e)(4) revised; eff. 10-15-79....4164
431.151—431.154 (Subpart D) Added....9753
431.200—431.250 (Subpart E) Added....17932
431.300—431.307 (Subpart F) Added....17934
431.503 (n) revised....17934
431.620 Added....17935
431.625 (c)(2) revised....17935
431.630 Added....16398
431.800 (h) revised....17935
431.801 Added....12591
Policy statement....12578
Effective date corrected....15494
432.55 (b)(3) revised....17935
432.60 (c) revised....17935
433.32 Added....17935
433.33 Added....17935
433.34 Added....17935
433.35 Added....17936
433.112 (b)(9) revised....17937
435.2 Undesignated text following (e) removed....17937
435.3 Amended; eff. 10-15-79....41437
435.403 Revised; eff. 10-15-79....41437
435.531 (a)(3)(ii) revised....17937
435.541 (b) and (c) revised....17937
435.724 (a) revised....17937
435.900—435.930 (Subpart J) Added....17937
435.1002 (b) revised....17939
435.1003 (a) revised....17939
436.1 Undesignated text following (d) removed....17939
436.2 Amended; eff. 10-15-79....41438
436.403 Revised; eff. 10-15-79....41438
436.531 (c) revised....17939
436.541 (b) revised....17939
436.900—436.909 (Subpart J) Added....17939
436.1002 (b) revised....17940
440.230 Revised....57253
441.50—441.90 (Subpart B) Revised; eff. 10-1-79 and 1-1-81....29424
441.100—441.106 (Subpart C) Added....17940

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Chapter IV—Continued

441.200 Revised....6717, 61598
441.204 Removed....61598
441.205 Amended....61598
441.250—441.259 (Subpart F) Effective date stayed to 3-8-79....5665
442.20 (b) revised....9753
447.45 Added....30344
447.205 Added....20695
447.261 (d)(4) and (5) removed....20696
447.306 Revised....20696
447.307 Removed; (b) transferred to 447.306 (c) and revised....20696
455.23 Redesignated as 455.202 and revised....31145
455.100—455.106 (Subpart B) Revised; eff. 10-15-79....41644
455.202—455.212 (Subpart C) Added....31145
456.11 (c) added; eff. 12-31-79....56337
456.601 Revised....56337
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